EpiSouth

Network for the Control of Public Health Threats
in the Mediterranean Region and South East Europe

Episouth plus project

WP7

SITUATION ANALYSIS ON COORDINATION OF SURVEILLANCE BETWEEN POINTS OF ENTRY AND THE NATIONAL HEALTH SYSTEM

Italy

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Acronyms

AO	Hospitals
ASL	Local Health Units
ARPA	Regional Agency for Environmental Protection
CD	Communicable Diseases
CNESPS	National Centre for Epidemiology Surveillance and Health Promotion
COA	Centro Operativo AIDS
DG	Directorate General
DM	Ministerial Decree
DPR	Decree of the Presidency of Ministers
ECDC	European Centre for Disease Control
EU	European Union
FCO	Fiumicino Airport
IHR	International health regulations
II.ZZ.SS	Veterinary Public Health Institutes
ISPESL	National Institute for Occupational Safety and Prevention
ISS	Italian National Institute of Health
ISTAT	Italian National Institute of Statistics
LEA	Essential Levels of Assistance
LHU	Local Health Unit
MD	Medical Doctor
MoH	Ministry of Health
NAS	Anti Fraud Squad – Carabinieri Headquarters for Healthcare
NFP	National Focal Point
NIPH	National Institute of Public Health
PIF	Posti di Ispezione di Frontiera/Border Inspection Posts
PoE	Point of Entry
RASFF	Rapid Alert for Food and Feed
SA	Situation Analysis
SOAR	Servizio Osservazione Analisi e Risposta – Observation, Analysis and Response Service
SOP	Standard Operating Procedures
SSN	National Health Service
ST	Steering Team
USMAF	Port, Airport And Border Health Office
WHO	World Health Organization
WP	Work Package

1. Introduction

1.1. THE EPISOUTH NETWORK

The EpiSouth Plus project is aimed at increasing health security in the Mediterranean area and South-East Europe by strengthening the preparedness for common health threats and bio-security risks at national and regional levels in the countries of the EpiSouth Network, in the framework of the International Health Regulations (2005) (hereinafter referred to as IHR).

With its 27 countries (10 EU and 17 non-EU) EpiSouth is the biggest inter-country collaborative effort in the Mediterranean region. Focal Points from each participating country have been appointed and asked for active involvement in the project's activities.

The project is organized in seven Work Packages (WP), each jointly co-led by an EU and a non-EU country/International Organization. WP leaders work in close contact with the corresponding WP Steering Team (ST), while a Steering Committee, constituted by all WP leaders, and the Project General Assembly, constituted by all participants, are responsible for the general strategic decisions. Finally, an Advisory Board, constituted by representatives of the collaborating institutions and external experts, provide support for the revision of relevant documents and recommendations.

1.2. WORK PACKAGE 7 – FACILITATING IHR IMPLEMENTATION

Work Package 7 (WP7 – Facilitating IHR implementation) of the EpiSouth Network is co-led by the World Health Organization (WHO) and the Italian National Institute of Health (ISS) with the guidance of a Steering Team (ST).

The goal of WP7 is to improve capacities required by the IHR , identified among those considered as priorities in the EpiSouth region. Its specific objectives are to identify capacities common to EpiSouth countries that need to be acquired or strengthened, to develop guidelines for the acquisition of these capacities and to advocate for access to resources needed for implementation of these capacities.

Through its yearly monitoring, WHO assesses in each country the level of implementation of capacities required by the IHR. However, the approach adopted is purely quantitative: no information on how the capacity was acquired is available. In addition, disaggregated data by region or group of countries is usually not made available by WHO, the 1st report of the EpiSouth Plus Project[1] being an exception.

Activities performed by the EpiSouth WP7 during the first two years of the EpiSouth Plus project led to the identification of an area needing priority attention for the implementation of the IHR in the EpiSouth Region: the **coordination of surveillance between Points of Entry (PoE) and National Health Systems**.

This aspect has been also recognized as a global priority, and WHO is therefore also developing global guidance on coordination of surveillance between PoE and National Health Systems. The EpiSouth WP7 Steering Team has been among the expert groups consulted in this process.

Literature on the topic is very scarce[2]. There is still a gap in information sharing of experiences and know how in this domain among countries.

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[1] *"Level of implementation of IHR 2005 in the EpiSouth Region: Analysis of WHO data and identification of priority areas", July 2011 available on the EpiSouth Plus website* http://www.episouthnetwork.org/sites/default/files/outputs/wp7-episouth_ihr_assessment_final-final.pdf

[2] *"In depth analysis of coordination of surveillance and response between points of entry and national systems in the EpiSouth region. Review of relevant scientific literature and of existing monitoring frameworks", December 2011 available on the EpiSouth Plus website* http://www.episouthnetwork.org/sites/default/files/outputs/wp7-

As stated by the WP7 ST in two meeting occasions (July 2011[3] and July 2012[4]), there is an added value in performing an analysis of anecdotic experiences and in sharing examples of how countries, facing similar problems in coordinating surveillance between Points of Entry and National Health Systems, approached and managed the functions required under IHR (through real-life illustrations). For this reason WP7 decided to perform a situation analysis to describe, among a selected number of countries, how coordination issues are addressed and which barriers are still in place. EpiSouth WP7 will therefore contribute to strengthening the coordination between PoE and national surveillance systems, by documenting how this works in selected countries of the EpiSouth network.

1.3. THE EPISOUTH NATIONAL SITUATION ANALYSIS ON COORDINATION OF SURVEILLANCE BETWEEN POE AND NATIONAL HEALTH SYSTEMS/MOH

The general approach chosen is that of a **national situation analysis of selected countries in the EpiSouth Region**. To keep the effort cost effective the analysis was not carried out on all 27 countries of the network, but on four countries chosen on the basis of their experience in the coordination of human health surveillance at PoE, their demographic and geo-political characteristics and their willingness to be part of the study.

As stated above, quantitative surveys are already carried out by WHO annually to assess progress in IHR implementation. This study was not aimed at duplicating this effort. In addition, countries present in the WHO workshop on coordination of surveillance between Points of Entry and National Health Systems advised not to propose additional quantitative surveys, suggesting to adopt methods that could provide qualitative information on how countries tackle coordination of surveillance[3]. The methodology was defined taking into account these considerations.

1.3.1. Objectives of the national situation analysis

General objective:

Contribute to improve the coordination of surveillance between Points of Entry (PoE) and National Health Systems (NHS) in the EpiSouth region, in the framework of the IHR .

Specific objectives:

- Describe how the exchange of information is organized between PoE and NHS in four countries representative of the diversity of the EpiSouth region;
- Identify formal procedures in place and legal constraints in these four countries,
- Describe main challenges and success stories in establishing a functional coordination of surveillance between PoE and national health systems in these four countries.

in depth analysis of coordination of surveillance and response between points of entry and national system.pdf

[3] *EpiSouth Plus project, First WP7 Steering Team Meeting, Rome, Italy, July 2011*

[4] *EpiSouth Plus Second WP7 Steering Team Meeting at the WHO 2nd informal consultation meeting on WHO technical advice for management of public health events on board ships, Lyon, France, April 2012*

2. Methodology

A full description of the methodology of the Situation Analysis (SA) is available in a separate text[5] uploaded on the EpiSouth Plus Website. Only specificities of the implementation of the analysis in Italy are hereby reported.

2.1. SELECTION OF ITALY AS ONE OF THE EPISOUTH COUNTRIES PARTICIPATING TO THE NATIONAL SITUATION ANALYSIS

Italy, an EU country, was selected among the roster of possible candidate countries for the SA because of its experience in coordination of surveillance activities between Points of Entry and the Ministry of Health. After the definition of the Terms of Reference for the participation in the study and the agreement of the country through its EpiSouth Focal Point and IHR National Contact Point, Italy was selected as representative of the second scenario depicted in Table 1. In Italy the EpiSouth SA investigator team had the possibility of studying how coordination of surveillance functions developed in a context with numerous administrative levels and a strongly decentralized health system.

Table 1 - Scenario categorization and participating countries

SCENARIO	EXPECTED IMPACT ON COORDINATION BETWEEN POES AND NATIONAL SURVEILLANCE SYSTEM	PARTICIPATING COUNTRIES
Small coastal states and islands	No or few ground crossings, numerous ports, few airports. Small countries with possibly fewer administrative levels/ overlapping professional functions.	Malta
Large States with extensive coastlines and federal or strongly decentralized health systems	All PoE present in large numbers, numerous administrative levels with diversification of competencies and greater coordination complexities.	Italy
States with no or little coastlines	Ports absent or very limited, higher importance of airports and ground crossings for which greater experience may have been gathered.	Jordan
Large States with extensive coastlines and centralized HS	All PoE present in large numbers, numerous administrative levels but central bodies	Morocco

2.2. COLLATION OF AVAILABLE DATA

In advance of the site visit, documents and data on the country's government structure, its surveillance system, the type, number, size and location of PoE as well as relevant legislation and official guidance documents concerning coordination of surveillance functions between PoE and the National Health System were collected.

A large number of official documents were freely accessible on the internet. The fact that both WHO and ISS investigators were fluent in Italian further facilitated the work.

[5] *National Situation Analysis on coordination of surveillance between points of entry and national health systems. Methodology and Workplan_Final Draft, February 2013*

2.3. PREPARATION AND EXECUTION OF THE SITE VISIT

Preliminary meetings were held, both via teleconference and face-to-face, among the EpiSouth investigators involved in the site visit (Gerardo Priotto, Flavia Riccardo and the EpiSouth National Focal Point Loredana Vellucci) to define how the processes, procedures and performance could be studied and more specifically what kind of events would be relevant to the study, i.e. would require bilateral communication between the MoH and the PoE.

As all Italian ground crossings fall under the Schengen agreement, they usually do not exercise control of the passage of people and only partially exercise control of the passage of goods (such as food and feed, live animals and animal products arriving by route directly from non-EU Countries). The national organizers therefore suggested that the team should focus on ports and airports. For this reason the site visit in Italy included the Italian MoH, the largest international airport (Fiumicino) and a large port (Livorno).

The EpiSouth National Focal Point identified the key actors and informants to be interviewed at each PoE to be visited, and established contact with them in advance. Interviewees received detailed information about the mission, in particular about the exact scope of the investigation, in order to avoid dispersion into the numerous activities of PoE that are not pertinent to human health surveillance. Interviewees were also informed in advance about the investigators' interest in obtaining copies of pertinent documents.

The EpiSouth National Focal Point initiated clearance procedures to enable the investigators to visit the PoE facilities, which required advance applications with personal documentation. The visits included meetings with presentations done by the investigators and the PoE staff and a tour of key facilities with on-going relevant operations in the PoE. Following this, the discussions focussed on the analysis of real-life examples of health events that had happened in the near past.

A briefing and a debriefing meeting were held at the Italian Ministry of Health (Central level) at the beginning and at the end of the site visit. These meetings involved the investigators of the SA and MoH officers in charge of epidemiological surveillance and of health at PoE. In the briefing meeting investigators were introduced through the officers' presentations to the Italian National Health System, the organization of national epidemiological surveillance for human health and of health at PoE. In the debriefing meeting the investigators presented to MoH officials preliminary findings.

3. Results

3.1. COUNTRY PRESENTATION

Italy is a peninsula located in southern Europe and is bordered by France, Switzerland, Austria and Slovenia. It has a population of 59.43 million (2011 census[6]). Italy is a parliamentary constitutional republic established in 1948 and divided administratively in 21 Regions and Autonomous provinces (hereinafter referred to as Regions) (Fig. 1), which differ in size, population and level of economic development[7].

Considerable powers, particularly in health care financing and delivery, have been progressively devolved to the Regions. Since the early 1990s, culminating in 2001 with a Constitutional Law[8], the responsibility for the provision of health services to the population has been gradually decentralized and the Ministry of Health, with the support of central technical bodies, has currently the responsibility to define with the Regional authorities the essential health services to be provided across the Country (Essential Levels of Assistance – LEA) as well as the methods and the quality standards to be maintained.

Each Region has its own budget for health, has the power to decide for the provision, within the public scheme, of additional services and additional quality standards, and is authorized to set its own reimbursement rates and to define how to allocate funds among its local health units and hospitals.

Figure 1 – Regions and Autonomous Provinces in Italy, 2013

The Italian National Health Service—Servizio Sanitario Nazionale (SSN) was established in 1978 (Law no. 833/1978) and offers tax funded universal coverage. Every person on Italian soil, irrespective of nationality, is entitled to access basic health care services. Residents are entitled to the largest spectrum of services either free of charge or at low cost through co-paying arrangements. Although public services cover most of the population's

[6] *Italian National Institute of statistics (ISTAT) "Il Censimento in pillole" Press release December 2012 (available at http://www.istat.it/it/files/2012/12/comunicato-stampa.pdf latest access 1/8/2013)*

[7] *Lo Scalzo A., Donatini A., Orzella L., Cicchetti A., Profili S., Maresso A. Italy Health system review. Health Systems in Transition Vol. 11 No. 6 2009*

[8] Constitutional Law n. 3, 18 Oct 2001

primary and secondary health-care needs, out of pocket paid private services are also commonly used, with some estimates suggesting that as much as 35% of the population uses some form of private health care[9].

Italy's public health system is organized in tree administrative levels: Central, including the Ministry of Health and National Technical Bodies, Regional, through the Departments and General Directorates for Health, and Local through Local Health Units (LHU) and Hospitals (AO). There are in total 21 First Level Administrative Units (one for each Region) and 146 Local Health Units. The organization of the Italian National Health System is shown in Fig.2.

Italy's designated national focal point for IHR is the Directorate General of Prevention of the Italian Ministry of Health[10]. Under this directorate fall two offices that are relevant to this study: the USMAF Central Coordination Office in charge of health at Points of Entry and the Communicable Diseases Office in charge of surveillance for human communicable diseases (hereinafter CD Office).

[9] *Paterlini M. Italy's health system reforms on hold. The Lancet Vol. 381 Issue 9872: 1085-1086*

[10] *The IHR was immediately applicable to the Italian domestic law based on a previous law (law 106 of the 9th of February 1982) and the NFP was designated on the basis of another precedent law (317 of 2001) whereby the functions of the MoH were defined (article 19 states responsibilities regarding Points of Entry and notifications to WHO).*

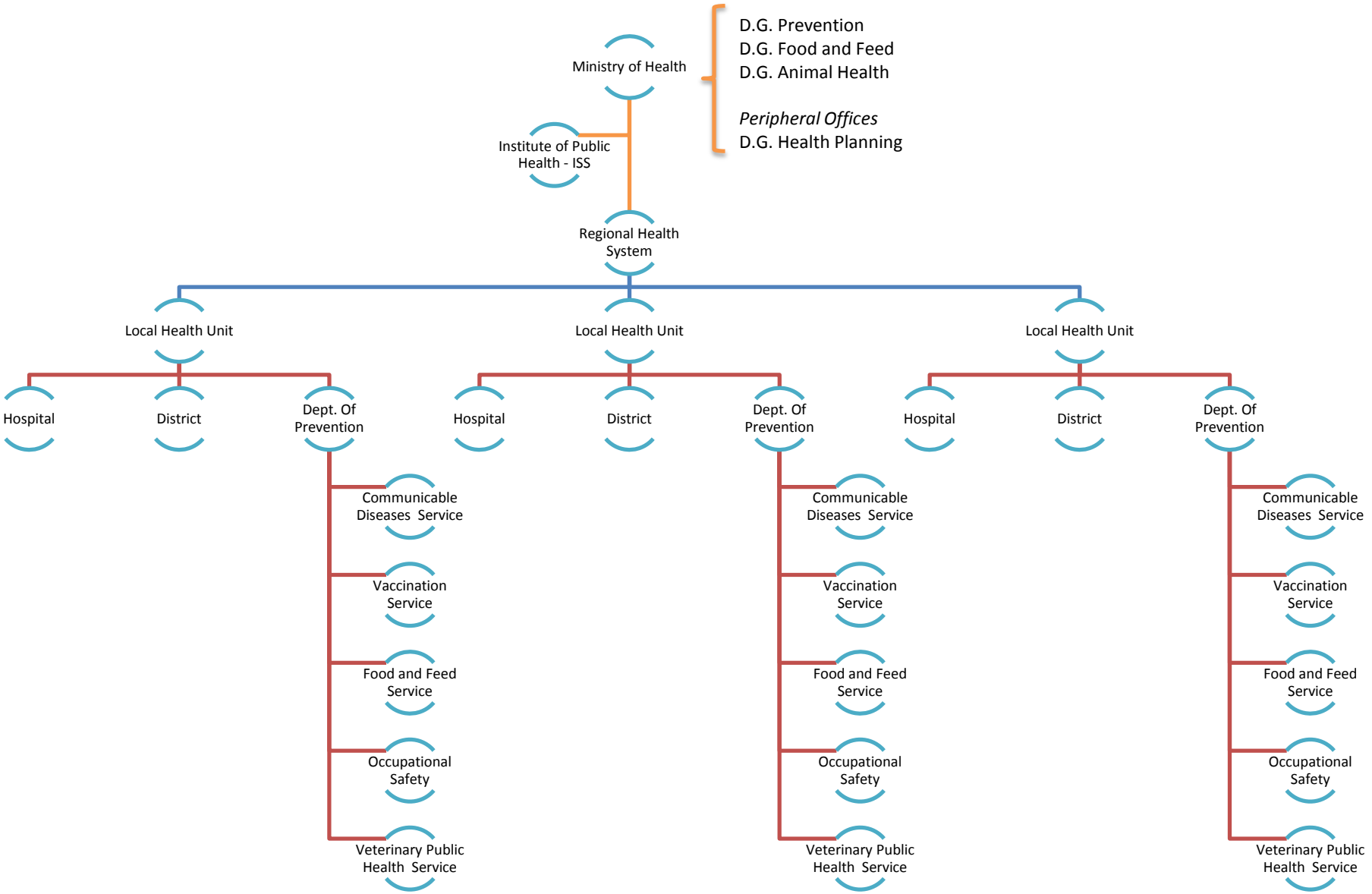

Figure 2 - Organization of the Public Health System in Italy, adapted from Italian Ministry of Health, personal communication

3.2. HEALTH AT POINTS OF ENTRY

Historically in Italy there has always been a strong tie between Health and Points of Entry. In the Middle Ages many Italian maritime cities set up Health Care Services close to ports and established health regulations with the aim of containing the frequent outbreaks of disease which decimated the coastal populations. First attempts were followed by progressively more efficient and stable interventions such as the establishment of the "lazzaretti". These fortified islands were built in the port area and forcibly hosted all arriving crew and passengers for a pre-established number of days to avoid the introduction of communicable diseases. This procedure was called "quarantine" from the Italian word "quaranta" meaning forty, which is the number of days ships were required to be isolated during the Black Death[11].

After the unification of Italy in 1861, Special Health Offices functioning as strategic sentinels of Public Health, were established in the most important ports [12]. These Offices were directed by a new kind of health authority: the Port Doctor, a government official in charge of different functions all closely related to maritime and frontier health. Over the years, these offices fell under the responsibility of the Ministry of Merchant Shipping and subsequently of the Ministry of the Interior. In 1958 the Ministry of Health was established[13] and the Special Health Offices were shifted under its responsibility.

With the birth of the National Health System (SSN) in 1978, many functions in the health sector were delegated to regional authorities, however the responsibilities related to cross-border healthcare at Points of Entry were kept at national level[14].

Figure 3 – Map of Italy colours distinguish the geographical territory of competence of 12 USMAF Main Offices (red dots). White dots indicate USMAF Branch offices. The star indicates the USMAF Central Coordination Office located in the Italian Ministry of Health (Central Level). June 2013, Ministry of Health, personal communication

[11] *Wikipedia Quarantine available at http://en.wikipedia.org/wiki/Quarantine (latest access 25/9/2013)*

[12] *Royal Decree no. 636 of 09.29.1895*

[13] *Law no. 296/58*

[14] *Law no. 833/1978 - Article 6, paragraph 1 - letter. A*

Italy has 31 designated ports, 24 designated airports (of which four "sanitary" airports) and one ground crossing. The Competent Health authority for PoEs in Italy is the Ministry of Health (Central level), which operates, in the field of human health, by means of the Port, Airport and Ground Crossing Health Offices (**USMAF- Uffici di Sanità Marittima, Aerea e di Frontiera**). The USMAF offices report to the USMAF Central Coordination Office that, as mentioned in section 3.1, is located in the Directorate General of Prevention of the Ministry of Health (Central level), which is also the IHR NFP.

Human Health controls at Points of Entry in Italy, aimed at limiting spread of infectious diseases and with responsibility on cross-border health of people, goods (drugs, food products of non-animal origin and dangerous products) and conveyances (mostly ships and aircraft), are managed by the USMAFs[15]. There is one Central Coordinating Office, 12 Main USMAF Offices and 37 USMAF Branch Offices that cater for a defined geographical territory (Figure 3 – Box 1) that at times coincides with, and others includes two or more, Italian Regions. Medical controls and requirements for conveyances are regulated by 13 different Standard Operating Procedures (SOPs) that set the relevant norms and legislation. The SOPs are available for consultation on the Italian MoH's website[16].

In the field of Veterinary Public Health the MoH (Central Level), and more precisely the DG of Animal Health, operates by means of 23 Border Inspection Posts called PIF – Posti di Ispezione di Frontiera[17] which are part of an EU network and are charged of health inspections on live animals and food products of animal origin at PoE. PIFs have guidelines that define procedures to be followed that are also available for consultation on the Italian MoH's Website[18]. These functions will not be addressed in detail in this study.

[15] *Italian Ministry of Health USMAF thematic area available at http://www.salute.gov.it/portale/temi/p2_4.jsp?lingua=italiano&tema=Prevenzione&area=usmaf (latest access 25/9/2013)*

[16] *Italian Ministry of Health USMAF Standard Operating Procedures available at http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3111&area=usmaf&menu=uffici (latest access 25/9/2013)*

[17] *Italian Ministry of Health PIF available at http://www.salute.gov.it/portale/ministro/p4_5_3_3.jsp?lingua=italiano&label=ufficiPeriferici&dir=pif&menu=organizzazione (latest access 25/9/2013)*

[18] *Italian Ministry of Health PIF Guidelines http://www.salute.gov.it/portale/ministro/p4_5_3_2_1.jsp?lingua=italiano&label=ufficiPeriferici&id=648&menu=organizzazione&dir=pif&p=guida (latest access 25/9/2013)*

BOX 1 – Organization, functions and staffing of USMAF Offices in Italy

The Italian Network of Port, Airport and Ground Crossing Health Offices (USMAF) comprises one USMAF Central Coordination Office (MoH Central level in Rome), 12 Main USMAF offices and 37 Branch offices (with two detachment offices), distributed across the country (Figure 3 and Table 2). The Central Coordination Office is also responsible for prevention and preparedness against biological, chemical and radio-nuclear terrorism, for coordination with the sector of Civil Protection for health aspects and for IHR related duties as it is headed by the IHR NFP responsible person for Italy.

Table 2 – List of USMAF offices as of June 2013

Main office	Branch Office	Geographical competence
Bari	Bari, Manfredonia, Taranto	Puglia (prov. Bari, Foggia, Taranto)
Bologna	Bologna, Ravenna	Emilia Romagna
Brindisi	Brindisi, Gallipoli	Puglia (prov. Brindisi, Lecce), Basilicata
Catania	Catania, Messina, Siracusa, Reggio Calabria, Augusta, Gioia Tauro	Sicilia orientale, Calabria
Genova	Genova ,Savona, Imperia, La Spezia	Liguria
Livorno	Livorno, Pisa	Toscana
Milano Malpensa	Malpensa, Torino Caselle, Bergamo, detachment Office of Linate; detachment office of Rivalta Scrivia	Piemonte, Lombardia, Valle D'Aosta
Napoli	Napoli Porto, Napoli Capodichino, Salerno, Cagliari, Porto Torres	Campania, Sardegna
Palermo	Palermo, Porto Empedocle, Trapani	Sicilia occidentale
Pescara	Pescara, Ancona	Abruzzo, Marche, Molise
Roma Fiumicino	Fiumicino, Civitavecchia, Roma, detachment Office of Ciampino	Lazio, Umbria
Trieste	Trieste, Venezia	Veneto, Friuli V. Giulia, Trentino, Alto Adige

The USMAF offices are in charge of health controls and preventive measures for in and out-coming international travelers, health and safety controls on conveyances, health controls on imported goods intended for human use or consumption (foods of non-animal origin, food containers, drugs, cosmetic products and dangerous goods such as radioactive substances and devices, dangerous gases and goods). occupational and forensic medical activity for applicants to the roles of Maritime Personnel, for seamen on duty and for the issue of nautical licenses. Some services are also offered online through the website of the Italian Ministry of Health.

As of January 2013, the personnel of USMAF offices in Italy was comprised of 88 Medical Doctors, 248 Health and Technical Professionals (including nurses, health inspectors and health technical officers) and 137 Administrative Staff.

Staff are continuously trained according to an **yearly USMAF Training Programme** managed by the USMAF Central Coordination Office. Trainings are aimed at updating the PoE staff on topics relevant to routine and emergency activities in their work environment. Training is also done via simulation exercises organized yearly.

In 2013 topics included medical management of radiological contamination, forensic medicine relevant to travel, and functioning of online databases used in the USMAF.

Further details of the yearly USMAF Training Programmes are available on the MoH website http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3067&area=usmaf&menu=vuoto (latest access 26/9/2013).

3.2. DETECTION AND MANAGEMENT OF HUMAN HEALTH RELATED EVENTS

Events of biological origin, e.g. infectious diseases occurring at PoE, are detected through surveillance activities under the responsibility of the Ministry of Health at Central level, and managed also by the MoH central level in coordination with the concerned Region/s. Conversely, the public health response to chemical and radio-nuclear events occurring at PoE are the responsibility of the local health unit/s of the NHS and primarily the Regional Agency for Environmental Protection (ARPA). Communication flows in this instance are managed mostly at the local level.

National coordination of plans and activities to detect and respond to Chemical and Radio-nuclear emergencies is ensured by the Department of Civil Protection[19] (as described in the Italian National Plan on Protective Measures against Radio-Nuclear emergencies[20]) in collaboration with other administrations, including the Ministry of Health (Central Level) for health related aspects. Due to this peculiar situation, the site visit to Italy focussed on biological threats.

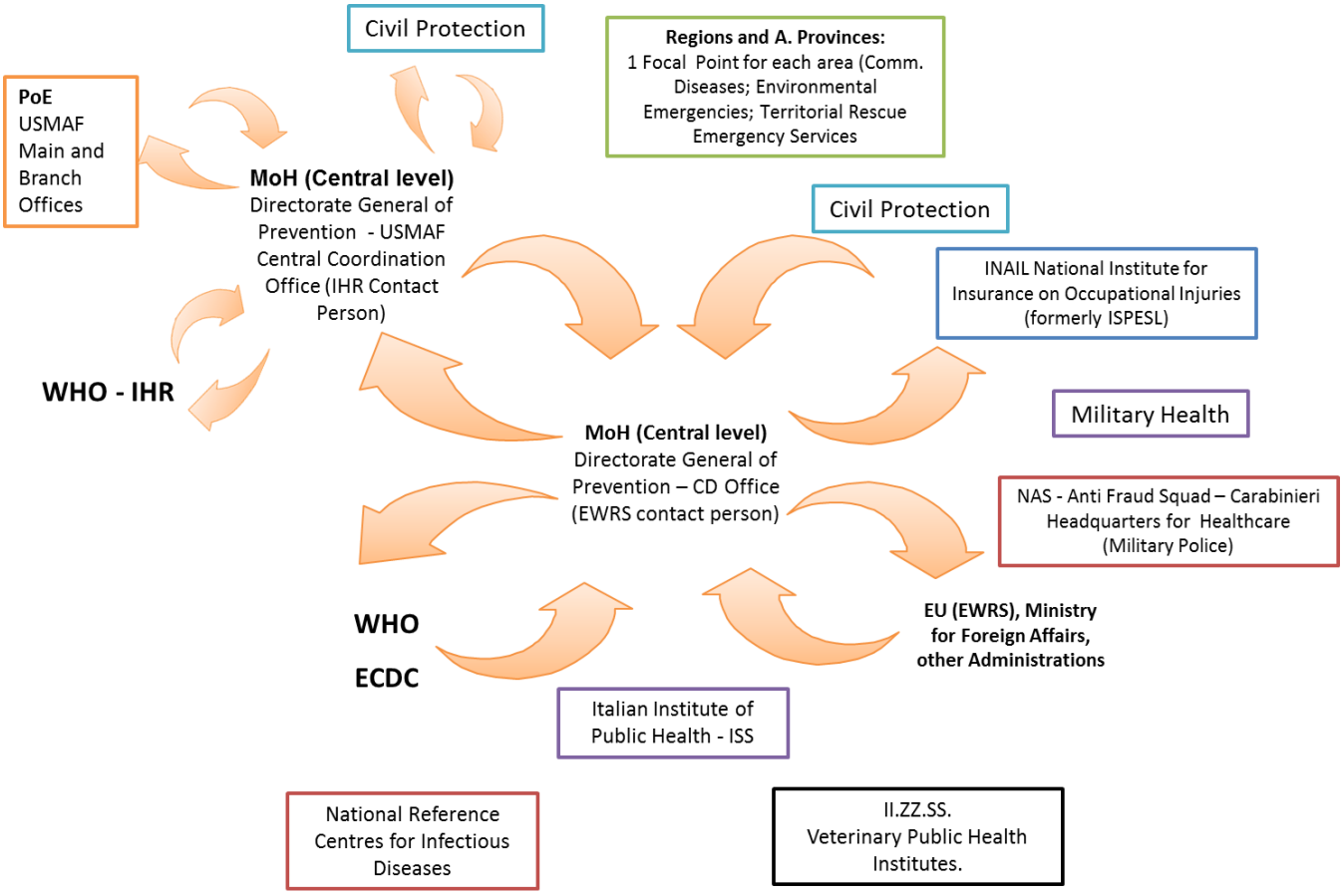

Figure 4 - Early Warning and Response System on communicable diseases: Partners. Adapted from Italian Ministry of Health, personal communication

[19] *Ordinance of the PM of the 28/3/03*

[20] *Italian National Plan on Protective Measures against RadioNuclear emergencies (available at http://www.protezionecivile.it/docs/www.ulpiano11.com/docs/Piano_nazionale_revisione_1_marzo_2010%5B1%5D.pdf)*

Numerous actors are involved in communicable disease detection and early warning and in outbreak/health emergency response. Their involvement differs whether the situation is classified or not as a national emergency. Figure 4 synthesizes the interaction between the main actors involved when the situation is not defined as a national emergency. Details of each partner is provided in the following sections in relation to the context in which they operate.

3.2.1. National Communicable Diseases Surveillance in Italy

3.2.1.1. Legislation

National surveillance for infectious diseases in Italy is currently governed by the Ministerial Decree of 15 December 1990 and subsequent amendments. The decree is currently under revision.

3.2.1.2. General organization

Diseases are regrouped in five notification classes. First class diseases require immediate notification (even pending laboratory confirmation), and include Viral Haemorrhagic Fevers, Cholera, Yellow Fever, Relapsing Fever, Plague, Poliomyelitis, Epidemic Louse Born Typhus Fever, Botulism, Diphtheria, Influenza (with viral isolation), Rabies, Tetanus, and Trichinosis. The communication requirements for each surveillance class across the different administrative units (local health units, regions and central level) are shown in Table 3.

Table 3 - Information flow by disease notification class

CLASS	EXAMPLES OF DISEASES IN THIS CLASS OF NOTIFICATION	STEP 1	STEP 2	STEP 3	STEP 4
1	Viral Haemorrhagic Fevers, Cholera, Yellow Fever, botulism, poliomyelitis , tetanus, trichinellosis,	MD→Local Health Unit (LHU) within 12 hours	Immediate notification from LHU→Region→ Ministry of Health (MoH) and National Institute of Public Health (NIPH)	Verification and immediate notification from LHU→Region→ MoH and NIPH →WHO as required	Compilation of specific notification form (model 15) LHU→Region→ MoH→ ISTAT (National statistics institute)
2	Brucellosis, Meningococcal meningitis; Chickenpox, Measles, viral Hepatitis	MD→LHU within 2 days	If required compilation of model 15 LHU→Region→ISTAT and MoH	Monthly data aggregates LHU→Region	Monthly data aggregates Region→ MoH, NIPH, ISTAT (model 16bis)
3	TB, non TB micobacteriosis, AIDS, Malaria, Leprosy	Individual information flow for: AIDS, TB, Malaria, Leprosy MD→LHU	LHU→ISTAT LHU→Region (monthly data)	For AIDS: Region→COA[21] (NIPH)[22]	Monthly data aggregates Region→ MoH, NIPH, ISTAT
4	Outbreaks of Scabies; food borne intoxications, Pediculosis	MD→ LHU only in case of disease clusters within 24 hours	Model 15 LHU→Region→ MoH, NIPH, ISTAT	-	-
5	Other diseases locally notified/ zoonosis indicated in the Veterinary Police regulations[23] and not mentioned in other classes	If in cluster within 24 hours else MD→LHU (no timeframe)	Annual summary LHU→Region→MoH	-	-

According to the type of disease, the information gathered is different. Diseases that are epidemic prone, particularly severe, in view to be eliminated/eradicated or biohazards that could be intentionally released require increased timeliness and higher detail of information compared with endemic and less severe conditions.

[21] *ISS - Centro Operativo Aids http://www.iss.it/ccoa/ (latest access 25/9/2013)*

[22] *Relevant legislation: DM 5 1987, DM48 1987*

[23] *DPR 8 Feb 1954, n. 320*

Moreover specific diseases such as HIV, TB and Malaria are notified in *ad hoc* notification forms that provide information on specific aspects such as risk factors, stage/type of disease and treatment[24].

In addition to the core surveillance system, other special surveillance systems are in place for diseases and/or populations which require specific attention (Influenza, West Nile Fever, Measles, Congenital rubella, Bacterial Infections, Meningitis[25] and syndromic surveillance in immigration centres[26].). Most of these complementary surveillance systems are managed in collaboration with the National Centre of Epidemiology, Surveillance and Health Promotion of the Italian Institute of Public Health (ISS - CNESPS)[27].

3.2.1.3. Actors involved in disease surveillance and public health event early detection in Italy:

- **Regions**: Italy has a decentralized health system, so focal points are present in each of the 21 First Level Administrative Units (Regions). The Regions through their local health units (LHU) are in charge of surveillance and outbreak response. In case of very large and/or multiregional outbreaks, support is provided by the Central level;
- **MoH (Central level) – Directorate General of Prevention**: The CD Office is in charge of routine surveillance activities[28]; the USMAF Central Coordination Office is in charge of surveillance in Points of Entry.
- **ISS-CNESPS: National Centre for Epidemiology, Surveillance and Health Promotion (CNESPS)** is part of the National Institute of Health (ISS). The mission of the Centre is to develop and apply epidemiological and bio-statistical methods to monitor and protect human health and to evaluate health services. The CNESPS is organized in 9 sections and 2 units. This includes the Unit for Communicable Disease Epidemiology that manages several special surveillance systems for communicable diseases.
- **ISPESL: National Institute for Occupational Safety and Prevention**: (now enclosed in the National Institute for Insurance on Occupational Injuries - INAIL): gathers information on accidents in the workplace, occupational hazards and diseases as well as on the different industries in the country in terms of the existing risk of exposure to health hazards;
- **II.ZZ.SS: Veterinary Public Health Institutes**: are in charge of surveillance of animal health detecting early increases in the reservoir of zoonotic infections;
- **NAS (Nuclei Antisofisticazioni e Sanità): Anti Fraud and Health Squad – Carabinieri Headquarters for Healthcare:** is a specialized unit of the Italian army[29] coordinated by the Ministry of Health. This unit is in charge of inspecting food and of goods intended for human consumption (drugs, cosmetics, devices etc...)[30] and environments where such goods are produced to make sure that all relevant regulations are respected. They have therefore the power to intervene as health inspectors in all places where products intended for the public are produced, distributed, deposited or sold.

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[24] *Further information on the Italian notification forms is available through the following link: http://www.simi.iss.it/modello_15.htm*

[25] *Istituto Superiore di Sanità La sorveglianza delle meningiti e delle altre malattie batteriche invasive in Italia. Rapporto 2005-2009. Gruppo di lavoro per la sorveglianza delle malattie batteriche invasive*

2012, iv, 34 p. Rapporti ISTISAN 12/25 (available at http://www.iss.it/binary/publ/cont/dodici25web.pdf)

[26] *Istituto Superiore di Sanità Emergenza immigrazione. Risultati della sorveglianza sindromica in Italia: maggio 2011 - aprile 2012.Flavia Riccardo, Christian Napoli, Antonino Bella, Caterina Rizzo, Maria Cristina Rota, Simona De Santis, Maria Grazia Dente, Monica Sane Schepisi, Maria Grazia Pompa, Silvia Declich e il gruppo di lavoro SorveglianzaSindromica Immigrati 2012, iv, 32 p. Rapporti ISTISAN 12/46 (available at http://www.iss.it/binary/publ/cont/dodici46web.pdf)*

[27] *I sistemi italiani di Sorveglianza Speciale. Annex 2 to the preliminary document for the EPIINT Project (report not available online)*

[28] *For further information consult http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=650&area=Malattie%20infettive&menu=vuoto*

[29] *Source of data http://www.carabinieri.it/Internet/Cittadino/Informazioni/Tutela/Salute/01_NAS.htm (latest access 26/9/2013)*

[30] *Relevant Legislation available at http://www.carabinieri.it/Internet/Arma/Curiosita/Non+tutti+sanno+che/N/11+N.htm (latest access 26/9/2013)*

- **USMAF: Port, Airport And Ground Crossing Health Offices**: The network of offices of cross-border health (maritime/airport/ground crossings) depends from the Ministry of Health (Central level) and is coordinated by the above mentioned USMAF Central Coordination Office. The network comprises 31 Branch offices, supervised by 12 Main Offices (see Box 1 for further details).

3.2.2. Public health emergencies

3.2.2.1. Legislation

The case of a public health emergency is regulated by law n. 225 (24th February 1992)[31] and described in the Italian pandemic influenza preparedness plan[32] (Fig. 5).

3.2.2.2. General organization

In case of a national emergency the Council of Ministers activates the **Department of Civil Protection** that in turn activates governmental and non-governmental actors such as the Italian Red Cross, the operational network of the emergency health response (118) and the Police forces.

Coordination shifts from the Ministry of Health (as shown in Figure 4) to the Civil Protection Department. If the emergency is health related, the Minister of Health will be called to provide technical advice as shown in Figures 5 and 6.

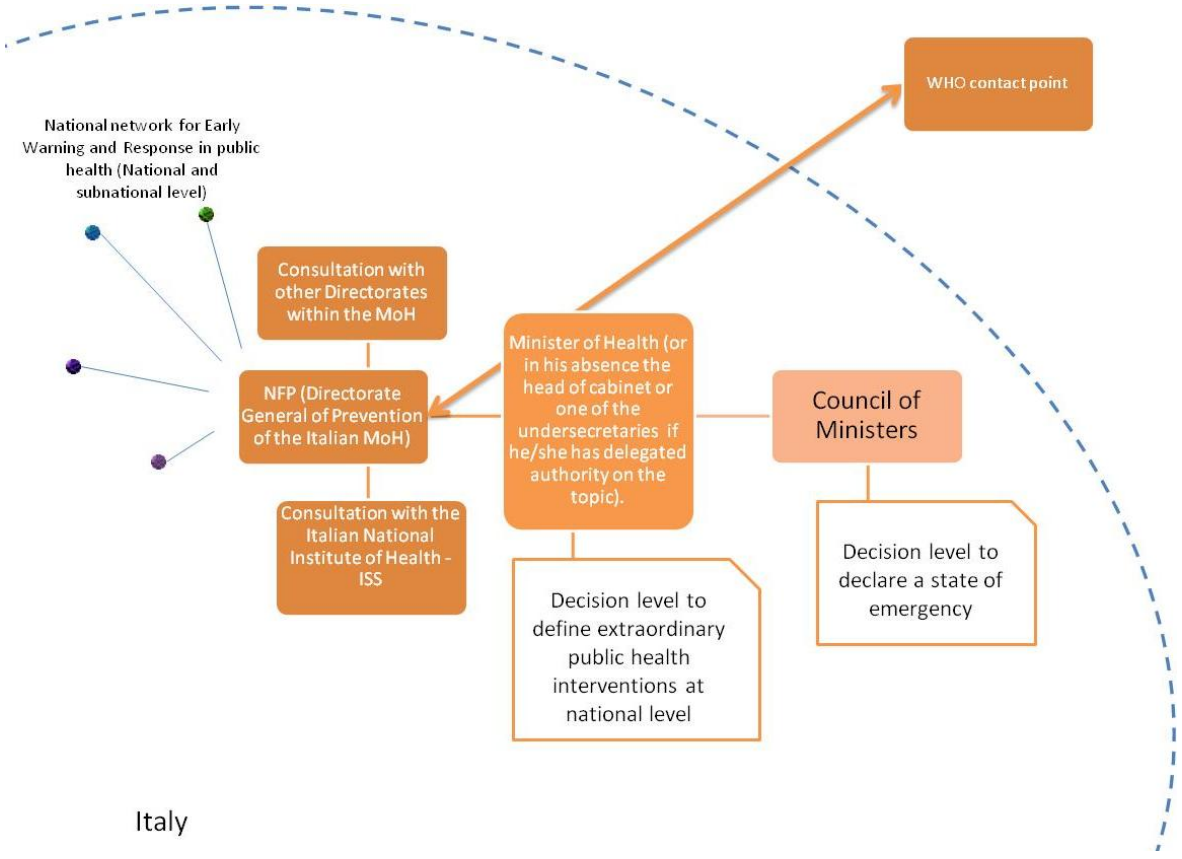


Figure 5 – Decision-making process and decision levels in case of public health emergencies in Italy as per the Italian Pandemic Preparedness Plan

[31] *Law n. 225, 24th February 1992 (full text available at http://www.protezionecivile.it/cms/view.php?dir_pk=41&cms_pk=137)*

[32] *Piano nazionale di preparazione e risposta ad una Pandemia influenzale (available at http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_allegato.pdf)*

3.2.2.3. Actors involved in risk communication, declaration and management of a public health emergency and outbreak control in Italy:

The following technical and political actors are involved in the declaration and management of a public health emergency at the National level.

- **Council of Ministers (also known as Italian Cabinet):** is the most important executive organ of the Italian Government. It includes the President of the Council (at times referred to as Prime Minister) and all the Ministers as well as the undersecretary to the President of the Council (who functions as secretary)[33].
- **Civil Protection Department:** is an office of the Presidency of the Council of Ministers. The Department coordinates the response to emergencies due to natural disasters, catastrophes or other events that, because of their intensity and extension, need extraordinary measures. In addition the Department has a role in drafting legislation on the prevention of risks and in defining the measures needed to cope with disasters minimizing the damage to people and property[34].
- **MoH – Directorate General of Prevention**: Is the National IHR Focal Point and is responsible for communicating timely with WHO on a possible PHEIC following the deadlines and procedures indicated in the International Health Regulations.
- **Consultation bodies within the MoH and the ISS**: liaise with the Directorate General for Communication and Institutional Relations; the Directorate General of Animal Health and veterinary drugs and the Directorate General of food security as well as relevant units within the National Institute of Health (ISS) including the Unit for Infectious Disease Epidemiology within the ISS-CNESPS described above.

[33] For further information consult http://www.governo.it/Governo/Struttura/cons_ministri.html (latest access 26/9/2013)

[34] For further information consult http://www.protezionecivile.gov.it/jcms/en/dipartimento.wp?request_locale=en (latest access 26/9/2013)

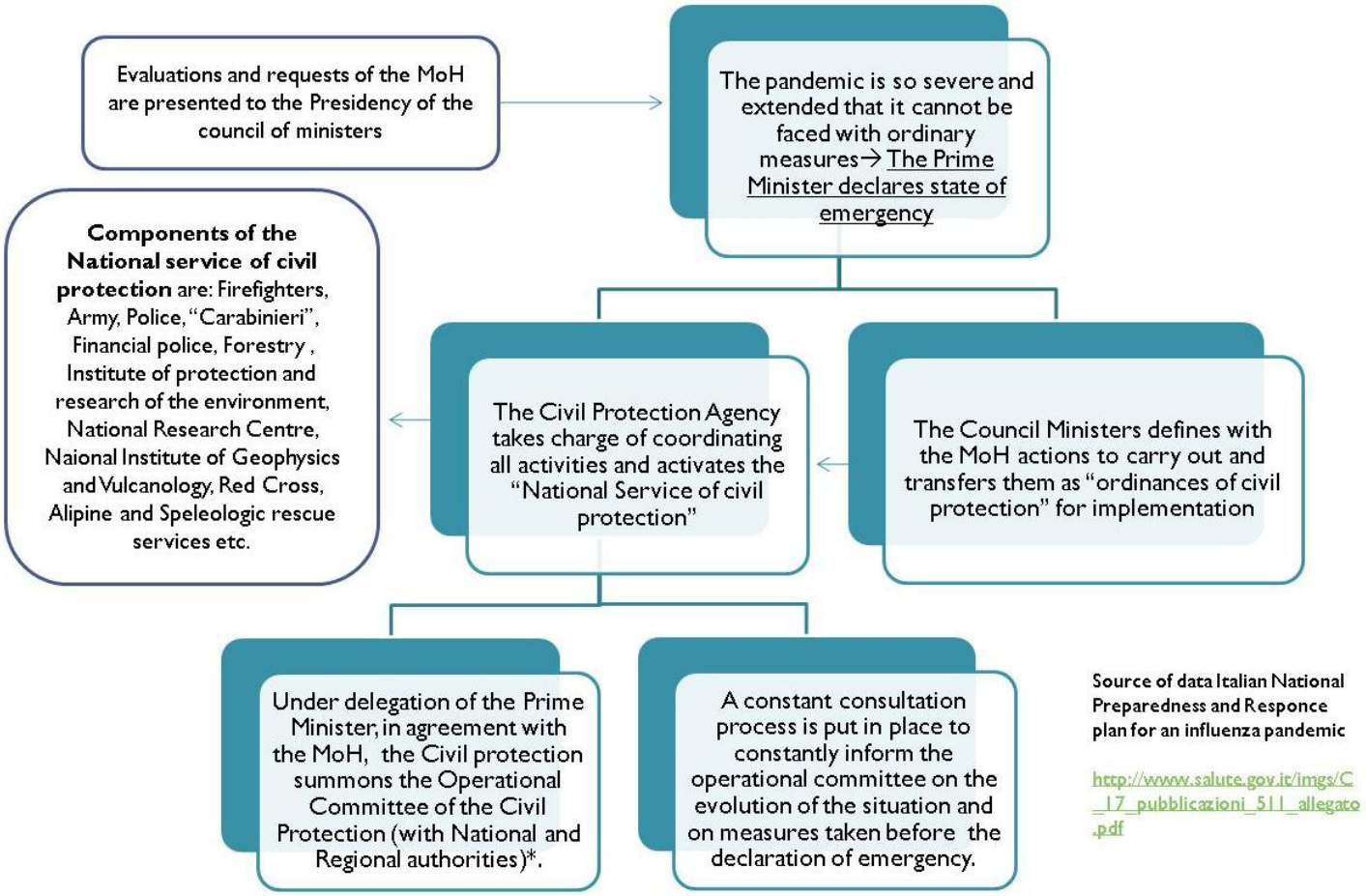
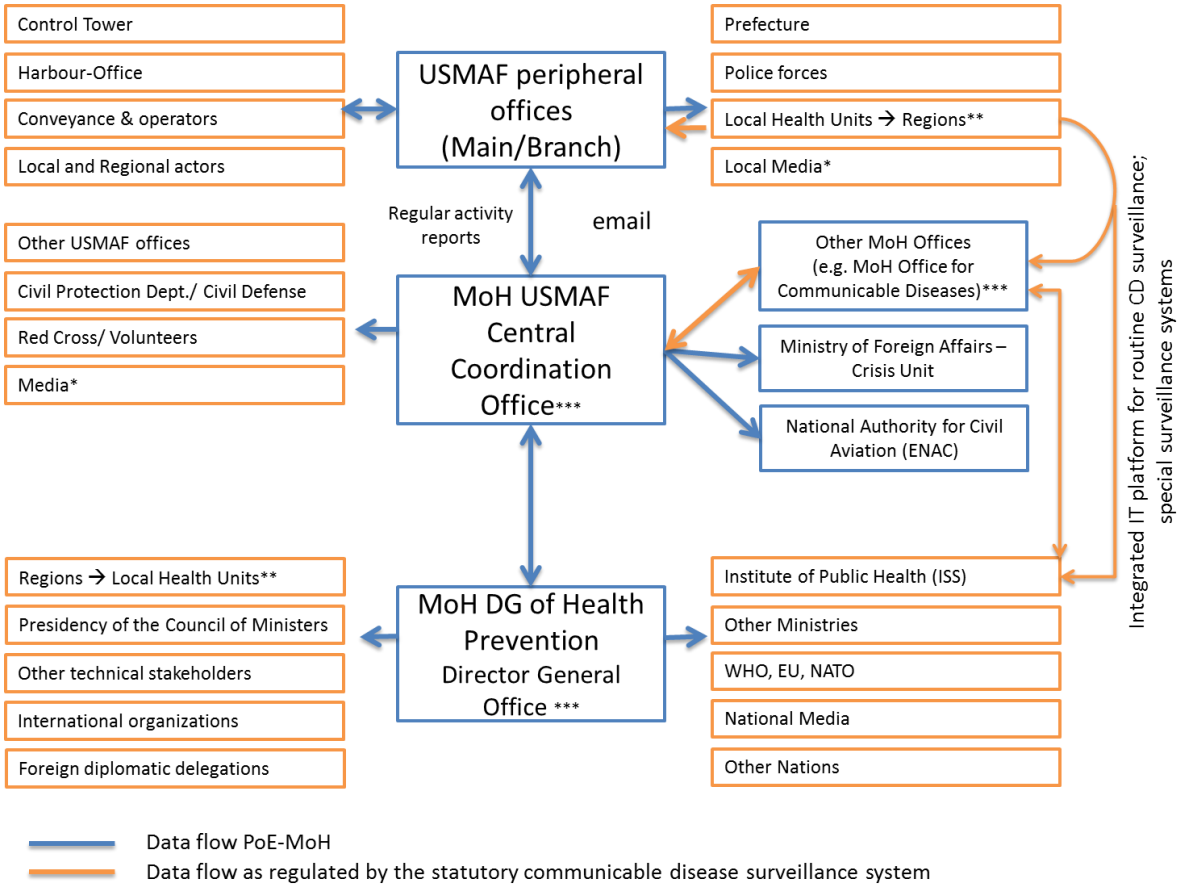


Figure 6 – Information flow and decisional chain as described in the Italian Pandemic Preparedness and Response Plan

3.3. COORDINATION OF HUMAN HEALTH SURVEILLANCE BETWEEN POINTS OF ENTRY (POE) AND THE ITALIAN MOH (CENTRAL LEVEL)

There are three main levels of communication in the coordination of surveillance between the PoE and the MoH (Figure 7): the USMAF Branch Office and Main Office level; the USMAF Central Coordination Office level and the MoH DG level.

Bilateral communication takes place between the peripheral USMAF Offices (Branch and Main) and the USMAF Central Coordination Office, mostly via email. The Central Office provides additional feedback to peripheral offices through regular USMAF activity reports (nation-wide, and sometimes also by USMAF office) which are published on the MoH website[35].



** The Press Office of the MoH manages all communications between the MoH and the media. The MoH DG of Prevention, the USMAF Central Coordination Office and the USMAF peripheral offices may liaise with the media only prior authorization from the Press Office; ** the Regions and Local Health Units appear twice in the diagram contacted at the local level by the USMAF peripheral offices and at the central level by the MoH DG of Prevention. In the first case the communication flow is between the USMAF and the LHUs, which in turn inform their Regions (bottom up). In the second case, the communication is started by the DG of Prevention which usually liaises first with the Regions (top down).; *** The MoH Offices of Communicable Diseases, the USMAF Central Coordination Office and the Director General Office here represented are all part of the MoH DG of Prevention.*

Figure 7 – Flow chart of communication between PoE and the MoH (blue); main actors involved and connections with the notification systems for communicable diseases (orange) – modified from "Documento di pianificazione centrale per la gestione delle emergenze interessanti gli USMAF"

[35] *Available at http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3065&area=usmaf&menu=vuoto and http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=961 (latest access 26/9/2013)*

The USMAF Coordination Office and the CD Office are both located in the same DG in the MoH. This creates a strong connection and consequently a defined data flow (highlighted in Figure 7). Therefore, should a case that has passed through a PoE undetected be diagnosed in a hospital/clinic/lab of the public health system, this information would reach the USMAF (at the Central Coordination Office or at the appropriate point in the network) through the existing routine and special surveillance systems.

We note the existence of a double information flow: disease events are reported by the peripheral USMAF both through the USMAF channel and through the local health units which will transmit the same information through the statutory health surveillance system (as described in section 3.2.1 of this report).

In addition to this formal communication framework, the USMAF Central Coordination Office in the MoH transmits events signalled by USMAF peripheral Offices plus relevant public health events detected through routine activities of web based Event Based Surveillance, in a standard format via email through a service called SOAR (Servizio Osservazione Analisi e Risposta – Observation, Analysis and Response Service). SOAR INFO bulletins are more general in scope and are sent to the USMAF Offices as well as other recipients mostly in public Italian institutions. Other SOAR bulletins are mostly restricted to an USMAF mailing list, focussing on maritime health (SOAR NAVI) or on health events involving air travel (SOAR AVIO).

3.3.1. Norms and Standard Operating Procedures (SOPs)

The coordination of human health surveillance at Points of Entry is regulated by a ministerial decree on communicable disease surveillance[36] and its subsequent amendments[37], described in detail in section 3.2.1 of this report.

An updated, documented and agreed upon National SOP for the management of emergencies at Points of Entry exists ("Documento di pianificazione central per la gestione delle emergenze interessanti gli USMAF" latest revision June 2009).

This document describes in detail who are the actors involved in a response to a health threat at PoE and defines general procedures for communication. On the basis of this national framework, USMAF Offices have derived context-specific and PoE-specific SOPs that include updated details of each member of staff's responsibilities, and contact details of relevant actors representing the detection and response capacity at the PoE. These documents were discussed during the site visits to PoE.

[36] *Ministerial Decree of the 15th of December 1990 (full text available at http://www.salute.gov.it/imgs/C_17_normativa_1357_allegato.pdf)*

[37] *Amendments to the DM 1990 (full text available at http://www.salute.gov.it/malattieInfettive/paginaInternaMalattieInfettive.jsp?menu=sorveglianza&id=650&lingua=italiano)*

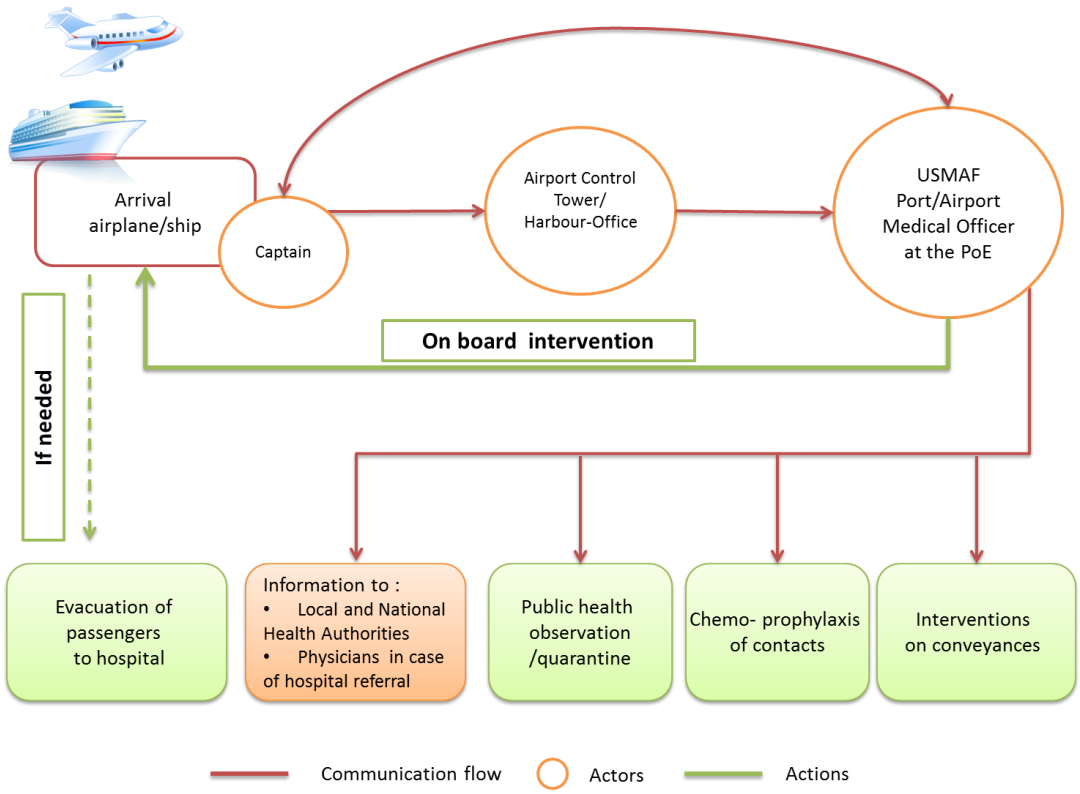


Figure 8 - Port and Airport Health Offices- Procedures, modified from MoH personal communication

3.3.2. General Organization

As shown in Figure 8, communication of a relevant human health event occurring on board a conveyance is initiated by the Captain of the airplane/ship to the airport control tower/harbour office. From here the USMAF Main or Branch office is contacted and the medical officer on call at the PoE initiates needed action to verify and manage the case, and informs local and national health authorities according to the communication lines shown in Figure 7.

3.3.3. Coordination of human health surveillance in the USMAF Central Coordination Office (Italian MoH Central Level) , Rome

The USMAF Central Coordination Office is located in the Ministry of Health (Central level), in Rome, and is part of the DG of Prevention.

The Office is charged of coordinating all the peripheral USMAF Offices and is also responsible, in collaboration with the CD Office of the same DG, of prevention and preparedness against biological, chemical and radio-nuclear events.

The USMAF Central Coordination Office is led by the Italian IHR Contact Person who is responsible of complying with international reporting requirements under the IHR.

Table 4 – Actors involved in the EpiSouth National Situation Analysis in Italian Ministry of Health Central Level

Actor	Present the MoH?	Notes related to relevance	Involved in the site visit?
IHR NFP	Yes	The Director of the USMAF Central Coordination Office was present and was one of the SA investigators	Yes
Operators in Public Health Surveillance	Yes	The Director of the CD Office was consulted	Yes
People in charge of PoE surveillance data management	Yes	In charge of the NSIS online database in which all USMAF Main and Branch Offices collect data on the inspection and forensic activities carried out at PoE	Yes

3.3.3.1. Legislation

The **USMAF Central Coordination Office** responds to all legislation mentioned in section 3.3 of this report. In addition it complies with the requirements of global and legal legislation such as IHR and EC regulations[38,39]. For further details consult the Legal Framework in annex to this report.

3.3.3.2. General organization

The USMAF Central Coordination Office is informed of events relevant to human health occurring at PoEs through the USMAF Main Offices across the country according to the processes described above and in line with Standard Operating Procedures that it produces and shares with all concerned parties (see section 3.3.1).

The Office owns and manages the **NSIS USMAF**, the online dedicated database used by USMAF offices across Italy. The NSIS USMAF (part of the wider platform of the New Sanitary Information System of the MoH) is an alert and networking tool that keeps track in real time of all routine activities carried out by USMAF offices. This is more than a register, because it enables offices to issue the required health clearance certificates through a guided process involving the insertion of specified data on imported goods and stakeholders involved. It is also used to keep track of identified contamination of food products to be reported in the EU RASFF (Rapid Alert for Food and Feed) portal[40].

Credentials to access the NSIS USMAF are granted only after a security accreditation and user rights on data access and activities differ according to the user profile. For example a Main USMAF Office will view data related to its Main and Branch Offices only, while the Central Coordination Office will view data from the entire USMAF Network. The Main and Branch Offices use the NSIS USMAF for their day to day duties, the Central Coordinating Office uses the information to coordinate activities, produce quarterly and yearly activity reports, available online on the website of the Ministry of Health[41], and to elaborate other reports for EU DGSANCO and/or for the Italian Parliament.

The USMAF Central Office provides feedback to the USMAF Main and Branch Offices both through ad hoc communications for specific events and through the SOAR INFO service described above. The Office also designs and delivers training to the USMAF staff (see Box 1).

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[38] Regulation (EC) No 882/2004 of 29 April 2004 On official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (In force in Italy from 01 January 2006)

[39] Regulation (EC) No 669/2009 of 24 July 2009 Implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC (In force from 25 January 2010)

[40] Rapid Alert System for Food and Feed (RASFF) Portal available at http://ec.europa.eu/food/food/rapidalert/index_en.htm (latest access 23/10/2013)

[41] USMAF Activity Reports http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3065&area=usmaf&menu=vuoto (latest access 27/9/2013)

Table 5 – Approximate number of reports per type of event that occurred at Italian PoEs in 2012 and status of transmission, as per the USMAF Central Coordination Office MoH (Central Level)

TYPE OF EVENT	NUMBER	N. TRANSMITTED TO PH AUTHORITIES (LOCAL/INTERMEDIATE)	N. TRANSMITTED TO THE IHR NFP
Reports for Communicable Disease Outbreaks	600	100	600
Reports for food safety events	15	NA *	15
Reports for Chemical threats	0	0	0
Reports for Radio-nuclear threats	0	0	0
Reports for zoonosis (animal)	0	0	0
Reports for zoonosis (human)	0	0	0
Reports for Chemical threats	0	0	0
Reports for Radio-Nuclear threats	0	0	0
Reports for Other (specify) threats	0	0	0

* Task under the responsibility of MoH (Central Level) DG of Food and Feed, Hygiene and Nutrition

3.3.3.3. Human resources

The USMAF network comprises 88 Medical Doctors, 248 Health and Technical Professionals (including nurses, health inspectors and health technical officers) and 137 Administrative Staff. The USMAF Central Coordination comprises a Chief (MD), three medical officers and 7 technical/administrative staff members (see Box 1).

The staff of the USMAF network has benefitted from the USMAF yearly Training Programme. It was described as adequately competent, but numerically insufficient to meet the duties assigned.

3.3.4. Coordination of human health surveillance in the International Airport "Leonardo Da Vinci"

The International Airport "Leonardo Da Vinci", FCO, is located in Fiumicino (Lazio Region) a short distance from the city of Rome. With a traffic of almost 37 million passengers in 2012 and 143 tons of cargo[42], it is the largest airport in Italy. Currently FCO is a hub catering for 63 different airlines reaching 265 destinations in 80 countries and 6 continents[43].

It was ranked the eighth busiest airport in Europe in 2012 based on passenger numbers[44]. Cargo is managed in a dedicated section of the airport called "Cargo City" equipped with inspection facilities for the control of live animals and animal derived food products (in particular fresh sea food).

Table 6 – Actors involved in the EpiSouth National Situation Analysis in FCO airport

Actor	Present the airport to be visited?	Notes related to relevance	Involved in the site visit?
Person in charge of human health surveillance (USMAF)	Yes		Yes
Person in charge of animal health surveillance (PIFs_ border inspection posts)	Yes		Yes
Person in charge of surveillance of food safety (USMAF/PIF)	Yes		Yes
Person in charge for surveillance of health hazards related to cargo (USMAF/PIF)	Yes		Yes
NGOs	No		No
Medical staff on conveyance (private/public)	-	Not relevant independent services	No
People in charge of conveyances (Occupational medical staff from air company Alitalia)	Yes	Not relevant independent services in contact with Local health Units and USMAFs	No
Border control professionals (Customs Officers)	Yes	In the process of integrating with USMAF and PIFs to streamline information systems and inspection procedures (Sportello unico doganale)	Yes
People in charge of the airport infrastructure (hub)	Yes	For health related aspects they work in close collaboration with local health units and USMAFs	No

The **Main USMAF Office of Roma Fiumicino** has responsibility over two Branch offices (one in Rome and one in the port of Civitavecchia) and a detachment in the airport of Ciampino (very close to Rome).

The procedures and processes for communication and coordination of surveillance of events relevant to human health follow the national communication flows described in Figures 7 and 8. For events occurring within the conveyances transiting through FCO airport, communication will occur through the Main USMAF Office. For events occurring in the airport premises, detected by health services located within the airport (e.g. air company occupational health services or the airport emergency unit), communication will occur through the Local Health Unit as part of the national statutory epidemiological surveillance system. In this case, the USMAF role will be to facilitate contact tracing, liaising with the airport staff and the airline companies.

[42] *Assaeroporti Statistiche* http://www.assaeroporti.it/2012/12/12-2012/

[43] *Source* http://www.theairdb.com/airport/FCO.html (latest access 26/9/2013)

[44] http://en.wikipedia.org/wiki/List_of_the_busiest_airports_in_Europe

The USMAF Fiumicino works in close contact with the FCO **Border Inspection Post (PIF)**[45] whose officers, veterinary doctors and health inspectors, inspect animal health and the safety of food products of animal origin (Figure 9).

Figure 9 – PIF officer checking cargo in FCO "Cargo City" with EpiSouth SA investigator

3.3.4.1. Legislation

The Health Part of the Aircraft General Declaration as per art. 38 of the IHR, fully endorsed by national legislation in Italy[46], is the keystone official documentation as to health conditions on board during an international voyage.

The Reference laboratory to which samples collected for inspection purposes are sent, is defined for the District Rome (Lazio Region) by the Regional Law n. 45 06/10/1998.

3.3.4.2. General organization

If a suspected communicable disease occurs on board a conveyance, the USMAF Fiumicino (which is the Competent Health Authority) is in charge of coordination of health interventions at the PoE and of communicating with all relevant actors according to the specific situation.

Any relevant event and health measure applied in the aircraft is transmitted to the USMAF Office by the pilot in command (or the pilot's agent) during flight or upon landing in the airport, The communication chain is described in Figure 8.

The USMAF Fiumicino mainly uses the email and the phone to communicate to the USMAF Central Coordination Office on these events. Conversely, data regarding the inspection activities carried out are collected in the

[45] *For further details consult* http://www.salute.gov.it/portale/ministro/p4_5_3_3.jsp?lingua=italiano&label=ufficiPeriferici&dir=pif&menu=organizzazione

[46] *The IHR was immediately applicable to the Italian domestic law based on a previous law (law 106 of the 9th of February 1982) and the NFP was designated on the basis of another precedent law (317 of 2001) whereby the functions of the MoH were defined (article 19 states responsibilities regarding Points of Entry and notifications to WHO).*

dedicated online database called NSIS USMAF managed by the Italian Ministry of Health at Central level and shared across all USMAF Offices (as described in section 3.3.3.2 of this report). In case of need, the USMAF peripheral offices may communicate with each other without prior authorization. The USMAF Central Coordination Office is copied in the message. International communications are managed only at the MoH by the USMAF Central Coordination Office or other concerned offices in the Ministry.

Response actions such as medical screening, isolation and evacuation from the airport to hospitals, take place in a dedicated structure called "Canale Sanitario" (Figures 11 and 12). This structure consists of a secluded zone equipped with medical and protective material, in which travellers can be screened in a fast and efficient way, before being allowed to join the public airport area, and where ill travellers can be isolated and transported safely to the appropriate hospitals.

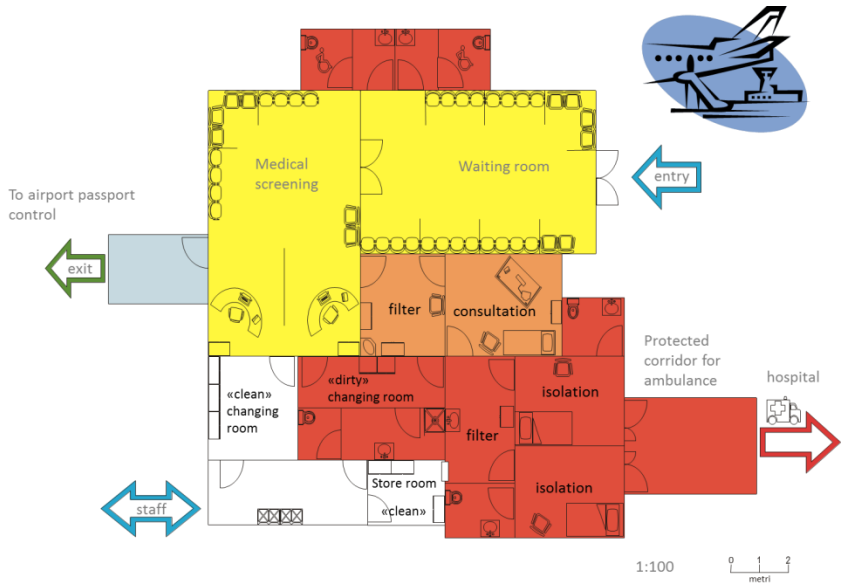


Figure 10 – Plan of the FCO airport "Canale Sanitario"- adapted from USMAF Main Office personal communication

Figure 11 – USMAF Medical Officer and dedicated ambulance in the FCO airport "Canale Sanitario"-

3.3.4.3. Human resources

The total staff of the Main USMAF Office of Roma Fiumicino and its branch offices comprises a Director, nine medical officers and technical/administrative staff according to the professional categories and with the duties described in Table 7. The staff of the Main Office in FCO airport includes three of the above mentioned medical officers plus the Director (MD).

Table 7 – Staff categories and main duties in an USMAF Main Office

Staff categories present in the Main USMAF Office-FCO	Assigned duties
Public Health Officers (MD) with Specialization in Hygiene, Sanitary Statistics, Aviation Medicine or in Infectious Diseases	• Medical consultations for any ill individual, • Medical screening of passengers (including immigrants) • Coordination of the inspection on conveyances and goods • Vaccination
Nurses, Health Care Assistants	• Vaccination • Collaboration in epidemiological investigations • Collaboration in providing first aid • Collection of biological specimen
Health Inspectors **Health Technical Officers**	• Controls on goods and collection of samples • Controls on conveyances • Assistance in, and inspection of, disinfection, disinsectation and deratting operations
Administrative personnel	• Administrative duties and communications

According to the USMAF Main Office Director, the number of trained staff assigned for Public Health detection/reporting/response at the FCO airport is insufficient, in particular the medical officers assigned to the main office, that have decreased over the years from 11 to four. Conversely, the staff's training possibilities on event surveillance, investigation and control at PoE was reportedly sufficient. Capacities of the staff were considered strong (Table 8).

Table 8 – Description of Staff Capacity, USMAF Main Office of Rome Fiumicino

	Poor	Modest	Strong	Not Applicable
Staff's knowledge of IHR and PHEIC			Yes	
Staff's knowledge of the epidemiological situation at PoE and capacity to assess PH risks				Data is analysed at central (MoH) level also for the Roma Fiumicino Territorial Unit[47].
Staff's knowledge of infection control techniques			Yes	
Staff's knowledge of reporting requirements of communicable diseases			Yes	
Staff's knowledge of CBRN threats			Yes	
Staff's knowledge of reporting requirements of CBRN threats			Yes	
Staff's knowledge of food safety measures			Yes	

[47] *USMAF di Roma-Fiumicino Organizzazione e attività 2012, Feb 2013 available at http://www.salute.gov.it/imgs/C_17_newsAree_2402_listaFile_itemName_4_file.pdf (latest access 27/9/2013)*

3.3.4.4. Psittacosis among FCO staff – a practical example of communication and coordination of surveillance

A real life situation involving coordination of communication in relation to surveillance of events relevant to human health was described by the staff at FCO airport during the site visit and is here reported.

Several years ago, two members of the FCO airport staff were diagnosed with Psittacosis in a nearby hospital. The information was relayed to the local health unit and from there to the Lazio Region and to the MoH Communicable Disease Office as per the national surveillance system (see section 3.2 of this report).

The Department of Prevention of the Local Health Unit investigated the working environment of the patients and found that both had worked at the airport in enclosures dedicated to the care and inspection of live animals and had handled a cargo of live parrots that had since left the airport.

The MoH Communicable Diseases (CD) office informed the USMAF Central Coordination Office and the MoH Veterinary services (head of the PIFs described above). The USMAF Central Coordination Office communicated with the USMAF FCO.

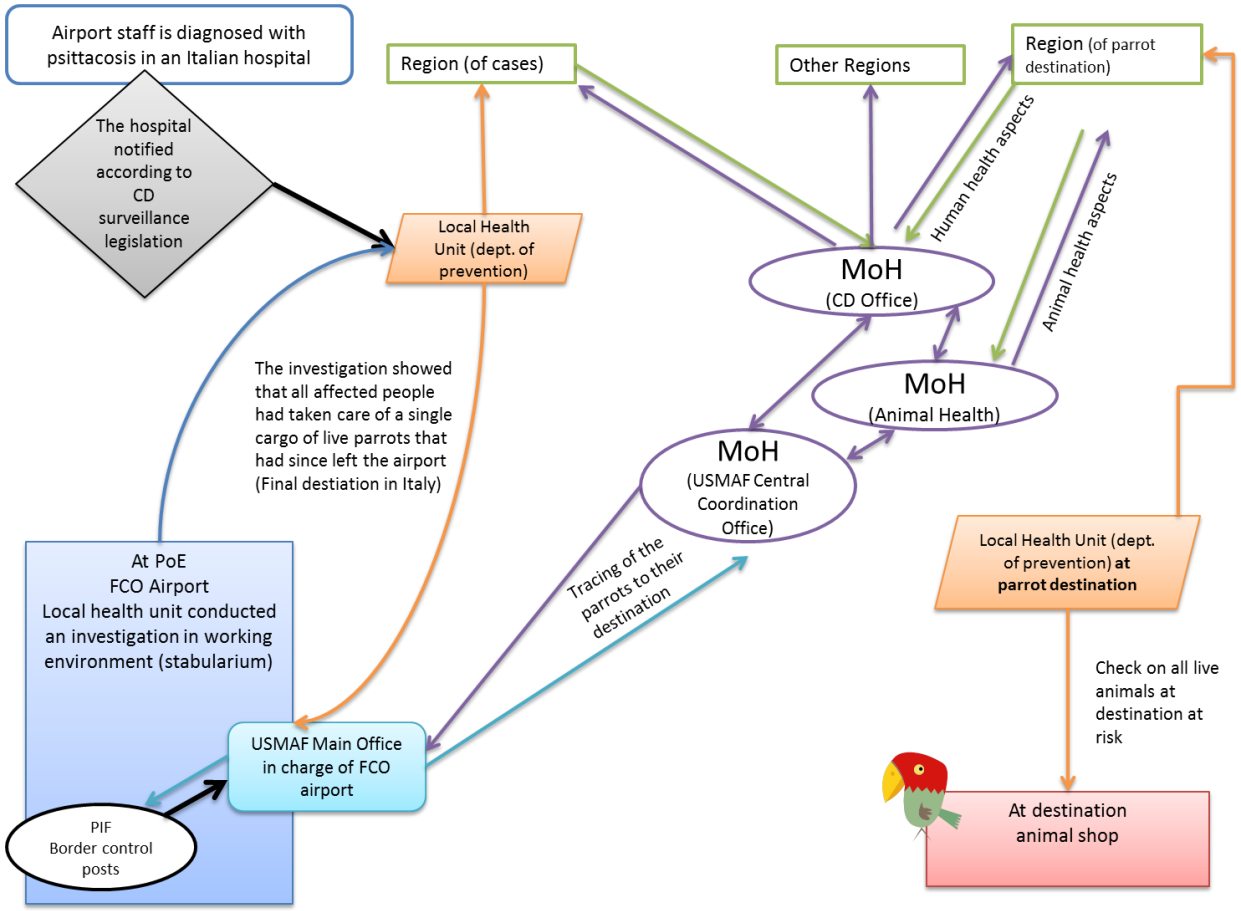


Figure 12 – Psittacosis among FCO operators: a real life example of communication coordination between MoH and PoE

The "Human" contact tracing and surveillance were performed by the Lazio Region in collaboration with the Local Health Units of Rome (Fiumicino is under the LHU Roma D). Information on the air carrier and exporter/country of origin was collected by the Veterinary Office, according to the rules on the controls of live animals and animal products.

The FCO PIF was able to identify the suspected cargo and its final destination thanks to its dedicated database on products received and inspection/control procedures (TRACES and NSIS SINTESI). The USMAF FCO also consulted its dedicated NSIS USMAF database on products received and inspection/control procedures[48].

All findings were communicated to the USMAF Central Coordination Office. After internal communication among the relevant offices in the MoH (Central level), the Region of destination of the parrots was contacted. The Region then alerted the local health unit (LHU) of the concerned area. The LHU coordinated the inspection of the pet shop that had received the parrots both for aspects concerning animal and human health (see organization of local health units described in Figure 2 of this report).

3.3.5. Coordination of human health surveillance at Livorno Port

The **Port of Livorno** is one of the largest seaports in Italy and in the Mediterranean Sea[49,50]. The port is structured in four basins: Avamporto, Porto Vecchio, Bacino Santo Stefano and Porto Nuovo.

Table 9 – Actors involved in the EpiSouth National Situation Analysis in Livorno port

Actor	Present Livorno Port?	Notes related to relevance	Involved in the site visit?
Person in charge of human health surveillance (USMAF)	Yes		Yes
Person in charge of animal health surveillance (PIFs_ border inspection posts)	Yes		Yes
Person in charge of surveillance of food safety (USMAF/PIF)	Yes		Yes
Person in charge for surveillance of health hazards related to cargo (USMAF/PIF)	Yes		Yes
NGOs	No		No
Medical staff on conveyance (private/public) (Agenzia Marittima MEDOV - cruises)	Yes		Yes
People in charge of conveyances (Agenzia Marittima MEDOW - cruises)	Yes		Yes
Border control professionals (harbour office – Capitaneria di Porto)	Yes		Yes
People in charge of the Port infrastructure (Livorno port authority)	Yes		Yes

[48] *For further information consult http://www.salute.gov.it/imgs/C_17_pagineAree_3146_listaFile_itemName_7_file.pdf*

[49] *http://www.porto.livorno.it/Info_porto.shtm*

[50] *http://www.ventoeporti.net/public/livorno.asp*

Figure 13 – Relevant Actors and EpiSouth Investigators during the site visit in the premises of the Livorno Port Authority

The USMAF Main Office of Livorno covers a territory that coincides with the Tuscany Region and comprises two Branch offices one in Livorno and one in Pisa.

3.3.5.1. General organization

In case of a suspected communicable disease on board a conveyance heading for the port of Livorno, the Main USMAF Office (which is the Competent Health Authority) is in charge of coordination of health interventions at the PoE and of communicating with all relevant actors according to the specific situation. Any relevant event, and health measure applied in the ship is transmitted to the USMAF Main Office by the ship captain before arriving to port, The communication chain follows the process described in Figure 8.

The USMAF of Livorno uses the email and the phone to communicate with the USMAF Central Coordination Office events relevant to human health occurring on conveyances. Data regarding the inspection activities carried out are collected in the dedicated online database called NSIS USMAF managed by the Italian Ministry of Health at Central level and shared across all USMAF Offices (as described in section 3.3.3.2 of this report).

In case of need, communication can occur directly between the USMAF Main Office and other USMAF peripheral Offices without prior authorization, but the USMAF Central Coordination Office is copied in the message. International communications are managed exclusively at the MoH Central level.

In case of a suspected outbreak on board a ship, the response initiates through the intervention of the medical officer on call at the USMAF Main Office who, after receiving initial communications from the ship and communicating the initial data to the Director, can board the ship and initiate an investigation with the help of the ship captain and the ship doctor. The USMAF Director will ensure the communication process described in Figure 7 is respected. In the Livorno Port, the USMAF staff coordinate with the PIFs who are in charge of animal health and of the inspection of food items of animal origin.

The USMAF Main Office of Livorno was called several times in the past years to intervene on infectious disease events occurring on maritime conveyances (Table 10) while no events of chemical or radio-nuclear nature were reported.

Written communications on individual incidents occur in four steps: an immediate report (called FLASH), a deferred report (called INFO), a number of intermediate reports (as needed), and a final report. The USMAF Main

Office staff indicated that all the events detected were fully reported to the Central Coordination Office (see Table 11 for 2012).

Table 10 – Communicable disease events in the port of Livorno, by type and by year

TYPE OF DISEASE EVENT	2011	2012	2013 (AS OF JUNE 2013)
Gastroenteritis	152	217	0
Chickenpox	22	7	2
Malaria	0	1	0
Sepsis	0	1	0
Pneumonia	0	1	0
Meningitis	0	4	0
Total CD events	**174**	**231**	**2**

Table 11 - Number of reports per type of event that occurred in the Port of Livorno in 2012 and status of transmission

TYPE OF EVENT	NUMBER	N. TRANSMITTED TO PH AUTHORITIES (LOCAL/INTERMEDIATE)	N. TRANSMITTED TO THE IHR NFP
Reports for Communicable Disease	**231**	**231**	**231**
Reports for food safety events	0	0	0
Reports for Chemical threats	0	0	0
Reports for Radio-nuclear threats	0	0	0
Reports for zoonosis (animal)	0	0	0
Reports for zoonosis (human)	0	0	0
Reports for Chemical threats	0	0	0
Reports for RadioNuclear threats	0	0	0
Reports for Other (specify) threats	0	0	0

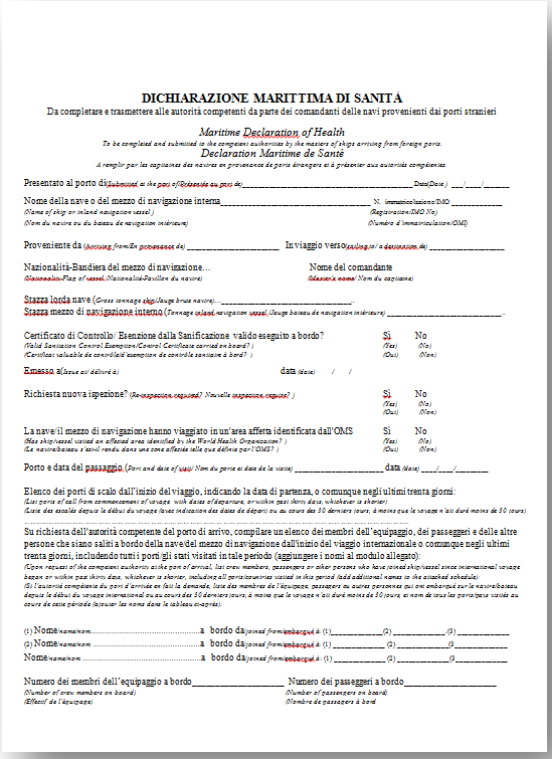
Comparing Table 11 with Table 5, it is clear that health related events occurring at PoEs are communicated to local and intermediate health authorities (LHUs and Regions) directly by the local USMAF Main and Branch Offices. Under 20% of events are communicated to Regions/LHUs by the USMAF Central Coordination Office at the MoH (Central Level). All events are transmitted to the IHR NFP (MoH). The MoH (Central Level) is in charge of all international communications.

3.3.5.2. Norms and Legislation

In the Port environment, the main official document related to health on conveyances is the Maritime Declaration of Health as per article 37 of the IHR . This is fully endorsed by national legislation in Italy (Figure 14).

If there is a sick passenger or crew staff on board a ship coming to port, this is communicated according to IHR and according to DPR 232/2001, the latest update of the Italian regulation concerning the release of *the free pratique* to the ships.

The subsequent measures are carried out in Livorno on the basis of a local SOP "Istruzione Operativa Locale 1012 «Comunicazione malato a bordo», updated on June 2010. The aim of this document is to establish a simple and specific procedure for timely and detailed information flows between the Livorno USMAF Staff, the USMAF Central Coordination Office and the MoH CD Office.



DICHIARAZIONE MARITTIMA DI SANITÀ

Da completare e trasmettere alle autorità competenti da parte dei comandanti delle navi provenienti dai porti stranieri

Maritime Declaration of Health

To be completed and submitted to the competent authorities by the masters of ships arriving from foreign ports.

Déclaration Maritime de Santé

A remplir par les capitaines des navires en provenance de ports étrangers et à présenter aux autorités compétentes.

Presentato al porto di/*Submitted to the port of/Présenté au port de*_____ Data/*Date* / ___ / ____ / _____

Nome della nave o del mezzo di navigazione interna/*(Name of ship or inland navigation vessel) (Nom du navire ou du bateau de navigation intérieure)*_____ N. immatricolazione/IMO/*(Registration/IMO No) (Numéro d'immatriculation/OMI)* _____

Proveniente da/*Arriving from/En provenance de)* _____ In viaggio verso/*sailing to/ à destination de)* _____

Nazionalità-Bandiera del mezzo di navigazione.../*(Nationality-Flag of vessel) (Nationalité-Pavillon du navire)* Nome del comandante/*(Master's name/ Nom du capitaine)*

Stazza lorda nave/*(Gross tonnage ship/Jauge brute navire)*:_____.

Stazza mezzo di navigazione interno/*(Tonnage inland navigation vessel /Jauge bateau de navigation intérieure)* _____.

Certificato di Controllo/ Esenzione dalla Sanificazione valido eseguito a bordo?/*(Valid Sanitation Control Exemption/Control Certificate carried on board?) (Certificat valuable de contrôle/d'exemption de contrôle sanitaire à bord?)* Sì/*(Yes) (Oui)* No/*(No) (Non)*

Emesso a/*(Issue at/ délivré à)* data/*(date)* / /

Richiesta nuova ispezione?/*(Re-inspection required? Nouvelle inspection requise?)* Sì/*(Yes) (Oui)* No/*(No) (Non)*

La nave/il mezzo di navigazione hanno viaggiato in un'area affetta identificata dall'OMS/*(Has ship/vessel visited an affected area identified by the World Health Organization?) (La navire/bateau a t-il rendu dans une zone affectée telle que définie par l'OMS?)* Sì/*(Yes) (Oui)* No/*(No) (Non)*

Porto e data del passaggio/*(Port and date of visit/ Nom du porte et date de la visite)* _____ data/*(date)* ____/____/_____

Elenco dei porti di scalo dall'inizio del viaggio, indicando la data di partenza, o comunque negli ultimi trenta giorni:/*(List ports of call from commencement of voyage, with date of departure, or within past thirty days, whichever is shorter) (Liste des escales depuis le début du voyage (avec indication des dates de départ) ou, au cours des 30 derniers jours, à moins que le voyage n'ait duré moins de 30 jours)*

_____

Su richiesta dell'autorità competente del porto di arrivo, compilare un elenco dei membri dell'equipaggio, dei passeggeri e delle altre persone che siano saliti a bordo della nave/del mezzo di navigazione dall'inizio del viaggio internazionale o comunque negli ultimi trenta giorni, includendo tutti i porti gli stati visitati in tale periodo (aggiungere i nomi al modulo allegato):/*(Upon request of the competent authority at the port of arrival, list crew members, passengers or other persons who have joined ship/vessel since international voyage began or within past thirty days, whichever is shorter, including all ports/countries visited in this period (add additional names to the attached schedule) (Si l'autorité compétente du port d'arrivée en fait la demande, liste des membres de l'équipage, passagers ou autres personnes qui ont embarqué sur le navire/bateau depuis le début du voyage international ou au cours des 30 derniers jours, à moins que le voyage n'ait duré moins de 30 jours, et nom de tous les ports/pays visités au cours de cette période (ajouter les noms dans le tableau ci-après):*

(1) Nome/*name/nom*.....a bordo da/*joined from/embarqué à*: (1)_____(2) _____(3) _____
(2) Nome/*name/nom*.....a bordo da/*joined from/embarqué à*: (1) _____ (2) _____(3_____
Nome/*name/nom*.....a bordo da/*joined from/embarqué à*: (1) _____ (2) _____(3_____

Numero dei membri dell'equipaggio a bordo/*(Number of crew members on board) (Effectif de l'équipage)*_____ Numero dei passeggeri a bordo/*(Number of passengers on board) (Nombre de passagers à bord)*_____

Figure 14 –Maritime Declaration of Health (first page) in use in the USMAF office of Livorno Port

3.3.5.3. Human resources

The Livorno USMAF Main Office comprises 3 MDs, 7 technical and 3 administrative staff while the Pisa Branch Office comprises 2 MDs, 3 technical and 2 administrative staff. The functions are those described in Table 7. Staff's professional capacity was described as strong, however the number of staff was described as insufficient.

Table 12 – Description of Staff Capacity, USMAF Main Office of Livorno

	Poor	Modest	Strong	Not Applicable
Staff's knowledge of IHR and PHEIC			Yes	
Staff's knowledge of the epidemiological situation at PoE and capacity to assess PH risks				Data is analysed at central (MoH) level.
Staff's knowledge of infection control techniques			Yes	
Staff's knowledge of reporting requirements of communicable diseases			Yes	
Staff's knowledge of CBRN threats			Yes	
Staff's knowledge of reporting requirements of CBRN threats			Yes	
Staff's knowledge of food safety measures			Yes	

3.3.5.4. Meningococcal Meningitis among the crew of a cruise ship – a practical example of communication and coordination of surveillance

A real life situation involving coordination of communication in relation to surveillance of events relevant to human health was described by the USMAF staff at Livorno port during the site visit and is here reported.

On a Sunday morning in October 2012 a cruise ship was arriving in Livorno Port while on a Mediterranean cruise. The previous port was Naples and the next one would be Villefranche in France. At 10 AM some crew members noted that an assistant waiter had not come to work in the morning and looked for him. They found him lying unconscious in his cabin with no other particular signs of disease. Thinking of an accident or maybe an overdose of drugs, the ship doctor ordered an immediate evacuation to the Livorno hospital where the patient arrived at 12:45.

Meanwhile a second crew member, a kitchen worker, was seen by the ship doctor at 12:00, in shock. Also this patient was evacuated to the Livorno hospital that he reached at 1:48 PM. Seeing two cases with neurological symptoms from the same ship, the doctors in the hospital suspected a communicable disease and performed a cerebrospinal fluid examination that led to the diagnoses of confirmed meningococcal meningitis. A notification (as per procedures of notification of communicable diseases) was sent from the hospital to the local health unit (LHU) and from there to the Region and the MoH (Central level) (see section 3.2 of this report).

At 2:30 pm the USMAF Main Office of Livorno was alerted by the LHU and half an hour later by the harbor office.

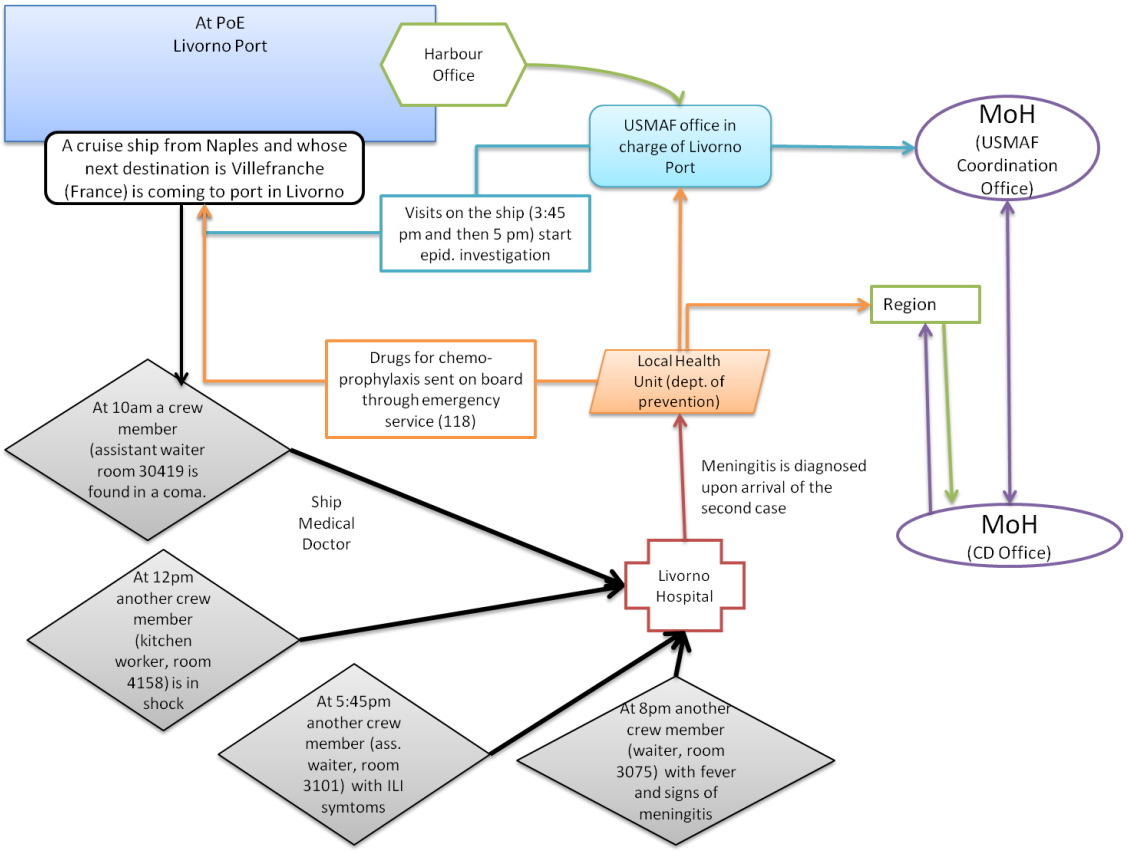


Figure 15 – Meningococcal meningitis among crew members of a cruise ship - a real life example of communication coordination between MoH and PoE

The medical officer on call at the USMAF Main Office of Livorno contacted by telephone the USMAF Central Coordination Office and conducted the first visit in the ship where he talked to the ship doctor and started the epidemiological investigation. At 5 PM he conducted a follow up visit on the ship during which he suggested the chemo-prophylaxis of all crew members and passengers.

A new case of illness was signalled at 5:45pm. The patient was another assistant waiter with influenza-like symptoms that was readily evacuated to the Livorno hospital reaching it at 6:30pm.

After 6pm the drugs for chemo-prophylaxis of meningitis were on board. At 8 pm a fourth crew member, a waiter, presented with fever and signs of meningitis. This patient also was readily evacuated and reached the hospital at 8:15pm.

The USMAF Medical Officer then provided technical advice to the ship, suggesting antibiotic prophylaxis to crew and passengers and permitting the ship to continue its trip. The Officer provided updates on the situation to the Harbour office, to the Maritime agency, to the USMAF-Livorno Director and to the MoH (Central Level) and compiled all the required technical digital and written forms. The next port of call, Villefranche, was alerted by the IHR NFP through the USMAF Central Coordination Office (MoH Central Level).

4. Discussion

The coordination of surveillance activities between PoE and the MoH/SSN in Italy is limited to communicable diseases, as the responsibility for surveillance of other classes of health threats fall under the mandate of other Administrations/Agencies and, in the case of a declared national emergency, of the Civil Protection in coordination with the MoH.

One of the strong aspects that emerges from this analysis is the solid link between the USMAF Main and Branch offices with the MoH (Central level), which enables a direct and rapid communication with the IHR NFP, in case the PoE staff detect a biological threat.

This stems from the historical precedence of health surveillance in the PoEs to the very existence of the Ministry of Health. The old links between the USMAF Main and Branch Offices with the MoH and the Italian National Health System have resisted the progressive decentralization of competences and responsibilities that has affected all other sectors of health care provision in the country.

We note that this system implies a double information flow. Communicable diseases are reported to the same DG of the MoH both by the USMAF channel and by the National Health System's statutory infectious disease surveillance. This implies that information on cases of infection connected to travel detected in the mainland can still reach the USMAF network backtracking this communication flow. USMAFs can then facilitate contact and cargo tracing, as described in the event reported by the USMAF of FCO airport.

Health related events occurring at PoEs are communicated to local and intermediate health authorities (LHUs and Regions) directly by the local USMAF Main and Branch Offices. Under 20% of events are communicated to Regions/LHUs by the USMAF Central Coordination Office at the MoH (Central Level). All events are transmitted from the USMAF Main and Branch Offices to the USMAF Central Coordination Office, that carries out the functions of IHR NFP. The MoH (Central Level) is in charge of all international communications.

Another strong point is the presence of standard, official and publicly available norms and protocols (SOPs) at central and local level. These documents clearly describe the roles, responsibilities and communication processes. This latter aspect is further confirmed by the fact that these processes were described identically by the staff at the MoH and PoE level during the site visit. At the PoE level, locally adapted SOPs with updated contact details of reference professionals were also available.

Communication between the PoE and the MoH occurs through email, telephone and structured databases. In addition to the official digital database for infectious disease routine surveillance at central (MoH) and Regional level, there are dedicated databases that document activities at the PoE and ensure the traceability of cargo and conveyances. The database used by the USMAFs is called NSIS-USMAF and the ones used by the Border Inspection Posts (PIF) are called NSIS_SINTESIS and TRACES. These tools greatly aid the USMAF Central Coordination and peripheral Offices involved in contact-tracing.

We found that the USMAF databases do not collect data on cases of human disease detected in the PoE in a structured form. Reports of events are prepared and stored in hard copy archives in the USMAFs. An analysis of disease trends by type of conveyance, by route, by operator or by season are not routinely made. An explanation generally offered was that this activity would require additional human resources which are not currently available.

In addition to this official circuit of formal notifications, informal information on events signalled by the various sources (USMAF Offices, routine surveillance, web event based surveillance, officers' personal communications) are sent by the Central Coordination Office to concerned stakeholders (USMAF Staff and Staff of other Italian

Public Institutions) through a service called SOAR (Servizio Osservazione Analisi e Risposta – Observation, Analysis and Response Service). This service, that focuses mainly on human health threats, was mentioned during the site visit by USMAF Main Office staff as greatly appreciated.

In Italy, PoEs have been assigned an entire network of health offices that work alongside the National Health System. This approach has led to a high performance, at the price of a large investment in terms of infrastructure and human resources. The staff in the USMAFs is highly selected and in constant training to ensure that all are confident and updated on actions expected both in routine and emergency situations. Trainings include courses and simulation exercises organized yearly on the basis of a central training programme.

Budget cuts have progressively led to a decrease in the number of human resources assigned to USMAF offices and this aspect has been described both at the Central level and at PoE level as the major current constraint the USMAFs are facing.

5. Annex

- Legal framework
- National Documents accessed
- Key informants
- Compiled Checklist
- Site Visit Agenda

5.1. LEGAL FRAMEWORK

5.1.1. International norms and regulations

- **International Health Regulations**
- **Schengen Convention**
- **Regulation (EC) No 882/2004 of 29 April 2004** *On official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (In force in Italy from 01 January 2006)*
- **Regulation (EC) No 669/2009 of 24 July 2009** *Implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC (In force from 25 January 2010)*

5.1.2 National Legislation

- **Regio Decreto 29 settembre 1895, n. 636** *approval of the regulation on maritime health with establishment of the first cross border health posts and of the port doctors.*
- **Unique Texts of the Health Laws 1907 and Regio Decreto 27/7/1934 n. 1265** *Framework laws on health in which the Royal Offices for Port and Airport health are established and subsequent modifications (Law 30 April 1962, n. 283; Decree of the President of the Republic 26 March 1980, n. 327)*
- **Regio Decreto 2/5/1940 n. 1045** *Approval of the regulations on Air-travel Health Police*
- **Article 32 of the Italian Constitution**
- **Law 23 December 1978 n° 833** *Health Reform*
- **Law n° 106/1982** *International Health Regulations*
- **Decree of the Minister of Health 2 May 1985** *Directives for the Regions and Autonomous provinces on international prophylaxis and public health*
- **Decree of the Minister of Health 14 February 1991** *Rights due to the MoH, ISS and ISPSL for service provision (and subsequent modifications: Decree of the Minister of Health 23 April 2003)*
- **Legislative Decrees 502/92 and 517/93** *Second Health Reform*
- **Legislative Decree 229/99** *Third Health Reform*
- **Law n° 405/2001** *State-Regions Agreement of 8 August 2001*
- **Constitutional Law 18 Oct 2001 n. 3** *Amendments to Title V - federalism – Devolution*
- **Law n° 317/2001**
- **Ordinance of the Minister of Health 27/12/2004**
- **Ordinanza congiunta UVAC-PIF/USMAF prot. 797/XXVII PIF/1/2007/06 USMAF 19 October 2007** *on catering on flights*
- **Decree of the Ministry of Health 19/12/2012** *aggiornamento degli importi delle tariffe e dei diritti spettanti al Ministero della salute per le prestazioni rese a richiesta ed utilita' dei soggetti interessati. (13A01312)*

- **Decree of the Prime Minister n. 242 04/11/2010** *Definizione dei termini di conclusione dei procedimenti amministrativi che concorrono all'assolvimento delle operazioni doganali di importazione ed esportazione (11G0008)*
- **Decree of the President n. 114 30/04/2010** *Regolamento recante modifiche al regio decreto-legge 14 dicembre 1933, n. 1773, convertito dalla legge 22 gennaio 1934, n. 244, concernente i requisiti visivi degli aspiranti alla iscrizione nelle matricole della gente di mare (10G0135)*
- **Circular of the Ministry of Health n. 35984 06/08/2009** *Esecuzione esami radiologici per l'accertamento dei requisiti di possesso di idoneità fisica(pdf, 0.25 Mb)*
- **Decree of the Ministry of Health, Labour and Social Policy 28/01/2009** *Revisione generale delle autorizzazioni all'imbarco quale medico di bordo e degli attestati di iscrizione nell'elenco dei medici di bordo supplenti (09A04799)*
- **Decree of the Ministry of Health n. 194 19/11/2008** *Disciplina delle modalità di rifinanziamento dei controlli sanitari ufficiali in attuazione del Regolamento (CE) n. 882/2004*
- **Decree of the Ministry of Health 12/09/2003** *Individuazione degli uffici dirigenziali di livello non generale*
- **Decree of the Ministry of Health 23/04/2003** *Aggiornamento delle tariffe dovute al Ministero della salute per prestazioni rese a richiesta dei soggetti interessati*
- **Decree of the Ministry of Health 17/05/2001** *Individuazione degli uffici dirigenziali non generali del Ministero della sanità*
- **Decree of the President 04/04/2001 n. 232** *Regolamento concernente la concessione della libera pratica alle navi*
- **Decree n. 271 27/07/1999** *Adeguamento della normativa sulla sicurezza e salute dei lavoratori marittimi a bordo delle navi mercantili da pesca nazionali, a norma della legge 31 dicembre 1998, n. 485*
- **Decree of the Ministry of Health 14/02/1991** *Determinazione delle tariffe e dei diritti spettanti al Ministero della sanità , all'Istituto superiore di sanità e all'Istituto superiore per la prevenzione e sicurezza del lavoro, per prestazioni rese a richiesta e ad utilitÃ dei soggetti interessati*
- **Decree of the Ministry of Health 02/05/1985** *Direttive alle regioni e alle province autonome di Trento e Bolzano in materia di profilassi internazionale e di sanita' pubblica (pdf, 0.07 Mb)*
- **Law n. 106 09/02/1982** *Approvazione ed esecuzione del regolamento sanitario internazionale, adottato a Boston il 25 luglio 1969, modificato dal regolamento addizionale, adottato a Ginevra il 23 maggio 1973*
- **Decree of the President n. 327 08/07/1980** *Regolamento di esecuzione della legge 30 aprile 1962, n. 283, e successive modificazioni, in materia di disciplina igienica della produzione e della vendita delle sostanze alimentari e delle bevande*
- **Law n. 283 30/04/1962** *Modifica degli articoli 242, 243, 247, 250 e 262 del testo unico delle leggi sanitarie, approvato con regio decreto 27 luglio 1934, n. 1265: Disciplina igienica della produzione e della vendita delle sostanze alimentari e delle bevande*
- **Regio Decreto n. 1773 14/12/1933** *Accertamento dell'idoneitÃ fisica della gente di mare di prima categoria (convertito con Legge 22 gennaio 1934, n.244)*
- **Regio Decreto n. 636 29/09/1895** *Approvazione del regolamento sulla sanità marittima*

5.2. RELEVANT NATIONAL DOCUMENTS

- Ministry of Health **Documento di pianificazione centrale per la gestione delle emergenze interessanti gli USMAF**, second revision June 2009
- ***Aggiornamento del Protocollo d'intesa tra l'Ufficio di sanità marittima, aerea e di Frontiera (USMAF) di Roma-Fiumicino del Ministero della salute e il Dipartimento di Prevenzione della A.s.l. RM D della Regione Lazio*** *per la ripartizione di competenze e la disciplina della collaborazione nell'ambito delle attività d'istituto attinenti l'aeroporto L. da Vinci di Fiumicino, July 2008*
- **Circolare serie aeroporti,** *APT- 27 Piano aeroportuale in caso di pandemie influenzali, November 2007*
- **Port of Livorno – Istruzione Operativa Locale – Comunicazione Malato a Bordo.** *operational from the 15th June 2010*

5.3. KEY INFORMANTS

Name	Institution	Location	Position
Loredana Vellucci	Italian MoH	Rome	Head of the USMAF Coordination Office, IHR National Contact Point, EpiSouth National Focal Point
Maria Grazia Pompa	Italian MoH	Rome	Head of the Communicable Disease Office; EWRS contact Point; EpiSouth National Focal Point
Virgilio Costanzo	Italian MoH	Rome	USMAF Coordination Office
Francesco Maraglino	USMAF Office	FCO Airport	Director of the USMAF office of Rome-Fiumicino
Alessandro Lattanzi	USMAF Office	FCO Airport	Staff of the USMAF Office
Francesco Morano	USMAF Office	FCO Airport	Staff of the USMAF Office
Vincenzo Fungaroli	PIF Office	FCO Airport	Border Inspection Post
Claudio Oliviero	Customs Office	FCO Airport	Director of the second Customs office of Rome
Linda Graziadei	USMAF Office	Livorno Port	Director if the Livorno USMAF office
Giusi Condorelli	USMAF Office	Livorno Port	Staff of the USMAF Office
Alessandra Salvatori	USMAF Office	Livorno Port	Staff of the USMAF Office
Maria Cristina Scardovi	USMAF Office	Livorno Port	Staff of the USMAF Office
Carmela Buonocore	USMAF Office	Livorno Port	Staff of the USMAF Office
Grazia Tasselli	PIF Office	Livorno Port	Border Inspection Post
Gianluca Vianello	Livorno Port Authority	Livorno Port	Head of the development unit of the port authority of Livorno

5.4. COMPILED CHECKLIST

CHARACTERIZATION OF THE NATIONAL SURVEILLANCE SYSTEMS AND COORDINATION BETWEEN POE AND NHS

1.1) Please indicate the number of designated PoE (provide a map if possible)

a.	**Ports**	28
b.	**Airports**	21
c.	**Ground crossings**	1

1.2) The Competent Authorities of PoEs report:

a. Directly to the IHR NFP
b. To local health authorities
c. To intermediate level health authorities
d. To other authorities: specify

1.3) Are there laws/norms in place that regulate coordination of surveillance between PoE and the NHS?

- **Yes**
- No

If yes can those laws/norms be made available to the investigator team?

1.4) Please indicate (for each item on the table) if there is an established link between PoE competent authorities in charge of event detection and the national surveillance system by answering the following questions:

Q1. Are coordinators designated?
Q2. Are regularly updated contact details available?
Q3. Is a decision instrument in place (to define what to detect and how – timing/modules/modalities)?
Q4. If yes, can this decision instrument be made available to the EpiSouth investigation team?

	Ports				**Airports**				**Ground Crossings**			
	Q1? (Y/N)	Q2? (Y/N)	Q3? (Y/N)	Q4? (Y/N)	Q1? (Y/N)	Q2? (Y/N)	Q3? (Y/N)	Q4? (Y/N)	Q1? (Y/N)	Q2? (Y/N)	Q3? (Y/N)	Q4? (Y/N)
Communicable Diseases under surveillance	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Chemical events	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Radiological events	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Food safety issues	**Y***	**Y***	**Y***	**Y***	**Y***	**Y***	**Y***	**Y***	**Y***	**Y***	**Y***	**Y***
Zoonosis (veterinary side)	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****
Zoonosis (human side)	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****	**NA****

* Only for aspects concerning the food imported from non EU Countries or food intended for consumption on international conveyances. All other situations fall under the responsibility of the local health authorities.

** This is mainly a task of regional and local health authorities.

1.5) Please indicate if there are legal constraints hindering coordination of surveillance between Points of Entry and National Health Systems.
No: The coordination of surveillance is put in place through the Directorate General of Prevention which, besides being the IHR NFP, has two Offices, namely the Office 03 and the Office 05, in charge respectively for the coordination of the USMAF (Health Offices at PoE) and surveillance of communicable diseases. In addition Office 04 is in charge of environmental health and chemical safety and Office 02 is in charge for RN issues.

1.6) Please indicate any interference/interaction/support of existing national plans in implementing/strengthening coordination of surveillance between Points of Entry and National Health Systems.
- Interference:
- Interaction:
- **Support**:

COMMUNICATION/COLLABORATION BETWEEN COMPETENT AUTHORITIES AT POINTS OF ENTRY, THE NATIONAL IHR FOCAL POINT AND HEALTH AUTHORITIES AT THE CENTRAL, INTERMEDIATE AND LOCAL LEVELS

2.1) Does the National IHR Focal Point have current contact details of all competent authorities at points of entry?
- **Yes (at central level, with Civil Aviation Agency (ENAC) the General Command of Coast Guard , the Ministry of transports, the Custom Agency)**
- No

2.2) Do local, intermediate and national Public Health officials involved in event surveillance and control have current contact details of all competent authorities at points of entry?
- **Yes (through the USMAF network)**
- No

2.3) Are current, regularly updated, documented and tested procedures for routine and urgent communication and collaboration during a public health emergency of international concern in place between the competent authority at PoE and:

- 2.3.1) : the competent authority at other points of entry
  - **Yes (central and local USMAF contingency plans)**
  - No
- 2.3.2) : health authorities (local, intermediate and national Public Health officials)
  - **Yes**
  - No
  - If needed specify
- 2.3.3) : other relevant government ministries, agencies, government authorities and other partners involved in points of entry activities
  - **Yes (collaboration protocols and local agreements)**
  - No
  - If needed specify

2.4) If the answer to questions 2.3.2 is "Yes", please specify if the communication occurs exclusively with the National IHR Focal Point or if also other health authorities are involved. **The Regional Health Authorities (NHS) are involved**

2.5) If the answer to questions 2.3.1- 2.3.3 is "Yes", please specify if the communication occurs both ways or is unilateral. **Bilateral**

2.6) If the answer to questions 2.3.1- 2.3.3 is "No", please specify

2.7) Describe the mechanisms in place in case of a potential PHEIC at PoE for reporting, assessment, confirmation and response specifying who is in charge of what (upload document word or ppt)

2.8) Do competent authorities at PoE:

	Ports (Y/N)	Airports (Y/N)	Ground crossings (Y/N)
Use the IHR assessment tool to decide if an event should be reported?	**YES***	**YES***	**YES**
Use another decision making tool tool that is applied in the same way throughout the country?			
Each use different decision making tools?			
Are national decisional procedures available at PoE?	**YES**	**YES**	**YES**
Are regional decisional procedures available at PoE?			
Are competent authorities public health officials?	**YES**	**YES**	**YES**
*** The Directorate General of Prevention, IHR NFP, use the IHR assessment tool**	**Note: Consider that the Health Authorities at Poe are within the Ministry of Health, but the reporting is made by the means of the central coordination offices (that is the Directorate General of Prevention)**		

2.9) Is capacity for detecting, reporting (within 24 hrs) a potential PHEIC and initiating response present in designated PoE?

- **Fully**
- Partially
- Not at all

2.10) Please indicate major gaps in human resources at PoE as relevant:

	Ports (Y/N)	Airports (Y/N)	Ground crossings (Y/N)
Number of trained staff assigned for Public Health detection/reporting/response not sufficient	**YES**	**YES**	**YES**
Staff have poor knowledge of IHR and PHEIC	**NO** (not true)	**NO**	**NO**
Staff have poor knowledge of the epidemiological situation at PoE and cannot assess PH risks	**NO**	**NO**	**NO**
Staff have poor knowledge of infection control techniques	**NO**	**NO**	**NO**
Staff have poor knowledge of reporting requirements of communicable diseases	**NO**	**NO**	**NO**
Staff have poor knowledge of CBRN threats	**NO**	**NO**	**NO**
Staff have poor knowledge of reporting requirements of CBRN threats	**NO**	**NO**	**NO**
Staff have poor knowledge of food safety measures	**NO**	**NO**	**NO**
Staff have poor training possibilities on event surveillance, investigation and control at PoE (staff at you PoE were not trained on these topics for over three years	**NO***	**NO***	**NO***

* *THE DIRECTORATE GENERAL OF PREVENTION ORGANIZES EACH YEAR AN EDUCATION AND TRAINING PROGRAM SPECIFICALLY DEVOTED TO THE USMAF*

5.5. AGENDA OF THE SITE VISIT TO ITALY

June 3 2013 (DAY 1)

	Activities
9:00 – 13:00	Arrival in Rome of the investigator team
13:30	Meeting at the Hotel Hall and Lunch (Optional and self paid)
15:15	Arrival at the Italian MoH
15:30 – 15:40	Presentation of participants
15:40 – 16:00	Presentation of the organization if the Italian MoH and surveillance activities of relevance to the EpiSouth situation analysis (involving the Points of Entry and the MoH and concerning risks to health relevant to IHR)
16:00 – 16:30	Presentation of the IHR NFP "USMAF The Quarantine Offices of the Ministry of Health. Facilities and Public Health measures at the Italian ports and airports"
16:30 – 16:45	Break
16:45 – 17:00	The EpiSouth Plus WP7 SA a brief overview
17:00 – 17:30	Overview of the site visit for the SA in Italy: planned activities and procedures

June 4 2013 (DAY 2)

	Activities
10:00 – 10:30	Arrival at the USMAF office in Fiumicino Airport (Rome) and presentation of participants. Overview of the day activities and approval of agenda.
10:30 – 11:30	Presentation of the USMAF office, ENAC, PIF and Customs activities and recent events relevant to IHR with if possible a focus on coordination of surveillance activities between the airport and the MoH (if possible following the checklist topics)
11:30 – 11:40	Break
11:40 – 13:00	Visit to the "Canale sanitario" (including the emergency room and airport ambulance) Visit to Cargo City (with Dogana e PIF tbc) for cargo related activities of the USMAF office
13:00 – 13:30	Lunch
13:30 – 13:40	Presentation of the EpiSouth Plus project
13:40 – 14:00	Presentation of the EpiSouth WP7 activities and of the Situation Analysis methodology and tools (EpiSouth WP7 investigation team)
14:00 – 14:20	Country Profile (EpiSouth Focal Point for Italy)

14:20 – 16:20	Case study for the mapping of the surveillance communication process in Fiumicino Airport
16:20 – 16:30	Break
16:30 – 17:00	Wrap up and conclusions

June 5 2013 (DAY 3)

	Activities
11:00 – 11:30	Arrival at the USMAF office in Livorno Port (Rome) and presentation of participants. Setting the scene of the EpiSouth situation analysis, overview of the day activities and approval of agenda.
11:30 – 12:20	Presentation of the USMAF office activities and recent events relevant to IHR with if possible a focus on coordination of surveillance activities between the port and the MoH (if possible following the checklist topics) and visit to the port structures
12:20 – 12:40	Country Profile (EpiSouth Focal Point for Italy)
12:40 – 13:30	Break
13:30 – 15:30	Case study for the mapping of the surveillance communication process
15:30 – 16:30	Wrap up and conclusions
17:16	Departure from Livorno

June 6 2013 (DAY 4)

	Activities

11:00 – 13:00	Debriefing of the investigator team in the Italian ISS
13:00 – 13:30	Lunch at the Canteen of the Italian ISS (Optional and self paid)
14:30 – 16:30	Debriefing at the Italian MoH: discussions and clarifications of findings and main lessons learned and challenges from the Italian experience in coordinating surveillance activities between PoE and the MoH.
20:00	Social Dinner (at the Hotel Globus Viale Ippocrate, 119 00161 – ROMA)

June 7 2013 (DAY 54949)

	Activities
10:00 – 12:30	Meeting of investigator team at the ISS on debriefing of the pilot study (what worked when can be improved), next steps in the SA
12:30 – 13:30	Lunch at the Canteen of the ISS (Optional and self paid)
14:00	Departure of participants